EFFECTIVENESS OF 3D FOOT SCANNER DESIGNED AND FABRICATED CUSTOMIZED FOOT INSOLE IN THE MANAGEMENT OF CHILDREN WITH FLAT FOOT

A PROJECT WORK SUBMITTED IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF OCCUPATIONAL THERAPY
(ADVANCED O.T. IN PAEDIATRICS)

Submitted by
Reg. No. 411613052

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION COLLEGE OF OCCUPATIONAL THERAPY

KOMARAPALAYAM - 638183

Affiliated to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI-600032

MAY – 2018

EFFECTIVENESS OF 3D FOOT SCANNER DESIGNED AND FABRICATED CUSTOMIZED FOOT INSOLE IN THE MANAGEMENT OF CHILDREN WITH FLAT FOOT

A PROJECT WORK SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF OCCUPATIONAL THERAPY
(ADVANCED O.T. IN PAEDIATRICS)

Submitted By
Reg. No. 411613052

**JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
COLLEGE OF OCCUPATIONAL THERAPY**

KOMARAPALAYAM-638183.

Affiliated to

**THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY,
CHENNAI-600032**

MAY – 2017

PRINCIPAL EXTERNAL EXAMINER

GUIDE INTERNAL EXAMINER

CERTIFICATE

This is to certify that the research work entitled **“EFFECTIVENESS OF 3D FOOT SCANNER DESIGNED AND FABRICATED CUSTOMIZED FOOT INSOLE IN THE MANAGEMENT OF CHILDREN WITH FLAT FOOT”** was carried out by **Reg. No. 411613052,** Final Year student, College of Occupational Therapy under JKK Munirajah Medical Research Foundation, Komarapalayam – 638183, in partial fulfillment for the award of Degree of **“Master of Occupational Therapy”** (Advanced O.T. in Paediatrics) of The Tamil Nadu Dr. M.G.R. Medical University, Chennai-32.

Mrs. R. RENUCHITRA. M.O.T., MDASLP,
Professor (Paediatrics)
JKKMMRF College of Occupational Therapy,
Komarapalayam.

Mr. T. JEGADEESAN. M.O.T., M.Sc (Psy)
Principal
JKKMMRF College of Occupational Therapy,
Komarapalayam.

Clinical Guide
Dr. VANATHI BALACHANDRAN MD., Pediatrics,
Asst. Professor, JKKMMRF College of Occupational Therapy
Komarapalayam.

CERTIFICATE

This is to certify that the Project work entitled **"EFFECTIVENESS OF 3D FOOT SCANNER DESIGNED AND FABRICATED CUSTOMIZED FOOT INSOLE IN THE MANAGEMENT OF CHILDREN WITH FLAT FOOT"** is a bonafied compiled work carried out by **Reg. No. 411613052,** Final Year student, College of Occupational Therapy under JKK Munirajah Medical Research Foundation, Komarapalayam – 638183, in partial fulfillment for the award of Degree of **"Master of Occupational Therapy"** (Advanced O.T. in Paediatrics) of The Tamilnadu Dr. M.G.R. Medical University, Chennai-32. This work was guided and supervised by **Mrs. R. RENU CHITRA, MOT., (Pediatrics) MDASLP** at the Department of Occupational Therapy, JKKMMRF, Komarapalayam.

Mrs. R. RENU CHITRA. M.O.T., (Paed), MDASLP,
Professor
JKKMMRF College of Occupational Therapy,
Komarapalayam.

ACKNOWLEDGEMENT

I am deeply indebted to My **LORD ALMIGHTY** for his abundant grace, unseen guidance and ceaseless bestowed upon me in all my endeavours and made my desire a reality which would have not been a possible otherwise.

I express my sincere thanks to **Dr. J.K.K.MUNIRAJAHH, M. Tech (Bolton)**, Correspondent **J.K.K.MMRF** College of Occupational Therapy for granting me this opportunity to complete my Master of Occupational Therapy course in their prestigious institution.

I express my deep sense of gratitude to **Mr. T. JEGADEESAN, M.O.T, M.Sc. (Psy),** Principal, **JKKMMRF** College of Occupational Therapy for his valuable guidance, encouragement and concern at every point which has been the driving force to complete this dissertation.

It is my great pleasure and privilege to record my sincere thanks to my Guide **Mrs. RENU CHITRA, M.O.T (Paediatrics), MDASLP,** Professor, **JKKMMRF** College of Occupational Therapy for her patience; constant support, inspiration and priceless guidance throughout this dissertation which made this study a great success.

My Special thanks to my Clinical Guide **Dr. VANATHI BALACHANDRAN, MD, PAEDIATRICS**, Asst. Professor, JKKMMRF College of Occupational Therapy.

My Sincere thanks to **Mr. K. DHANAPAL, Statistician**, **JKKMMRF** College of Occupational Therapy for the valuable help he offered in Statistical Analysis.

I extend my thanks to **All the College Staffs, Department Faculty Members, Office Staffs** and **Librarian, JKKMMRF** College of Occupational Therapy who gave me a helping hand to do this project.

I owe to express my gratitude and sincere thanks to **THE LEPROSY MISSION TRUST INDIA,** for funding this project and sponsoring myself for Master degree.

I have no words to express my thanks to **Mr. MANIVANNAN**, Programme Manager, **PARTI** Project, **Mr. KARTHICK**, Co-ordinator **Research Domain**, **Mr. MATHANRAJ David,** Programme Manager, **CREATE** Project, **Dr. MS. RAJU, Research Scientist**, Research Domain, **Mr. RAJA,** Physiotherapist **CFAB** project, **Mr. SHAM KUNNATHDASS**, Prosthetist and Orthotist, **CFAB, The Leprosy Mission Trust India. Mr. SATHISH PAUL,** Physiotherapist cum Podiatrist, Head of Physiotherapy Dept. **SLRTC**, Karigiri.

My sincere thanks to **Dr. CHINNARAJU**, Medical Superintendent, Leprosy Mission Hospital, Vadathorasalur, **Dr. JERRY JOSHUA**, Head Health, New Delhi, **Mr. MELVIN MORIS,** Head HR, New Delhi, **Dr. MERCY BERRY**, Paediatrician, Leprosy Mission Hospital, Vadathorasalur, **Mr. BINO BERRY,** Co-ordinator POID, **Mr. RAM K ROBERT** Programme Manager CREAT Project.

And also I express my thanks to my family members especially my daughter **MANSI,** Batchmates, **Mrs. G.SRINITHYA, Mr. GANAPATHY, Mr. RICHU JOSEPH** and friends for their constant support, encouragement and co-operation.

My special thanks to **STAFFS** of The Leprosy Mission **PARTI** Project and **Early Intervention Centre,** Chidambaram Block.

Last but not least I thank all the **Children and Parents** who took part in the study. Without them this study couldn't end up with success.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

ABSTRACT

OBJECTIVE:

The purpose of the study is to evaluate the effectiveness of 3D foot scanner designed and fabricated customized foot insole in the management of children with flat foot.

METHODS:

In this study a total of 30 children from the age of 6 to 10 years with flat foot participated and were divided into 15 each in experimental and control group. The Foot Function Index (FFI) and Oxford Ankle foot Questionnaire (Parent Version) were used for both the groups at the start of the intervention and later after 4 months after intervention. The 3D foot scanner designed and fabricated customized foot insole was used as an intervention in the management of children with flat foot for 4 months duration and the data were recorded and analysed for statistical analysis.

RESULTS:

In control group Foot Function Index (FFI) pre-test score are56 (5.58) and post test score was 55.80(5.89) and Oxford Ankle foot Questionnaire Pre-test scores were 18.73 (5.04) and post test score were 18.73 (5.32). Whereas in Experimental group Foot Function Index (FFI) pre-test score was 55.40 (8.36) and post test score was 41(7.92) and Oxford Ankle foot Questionnaire Pre-test scores were 15.80(6.18) and post test score were 27.60(5.37). The paired t test for the experimental group for Foot Function Index (FFI) is ($p < 0.01$) and Oxford Ankle foot Questionnaire was ($p<0.01$).

CONCLUSION:

The findings of the study suggest that 3D foot scanner designed and fabricated customized foot insole is effective in management of children with flat foot.

KEY WORDS:

Flat foot, Heel Valgus, Navicular Height, insole, Medial arch, 3D foot Scanner, Foot Function Index, Occupational therapy intervention.

Flat foot (pes planus) is one of the most common conditions observed in children. The true prevalence of flat foot is unknown, primarily because there is no consensus on the strict clinical or radiographic criteria for defining a flat foot[38].

Flat foot is defined as absence of an arch in the sole of the foot that causes the foot to lie flat when the person is standing.

Prevalence of flat foot is highly variable in different populations. This variability is influenced by various factors. Those can be divided into two; internal and external factors. The internal factors are age, gender, genetics and developmental milestones while the external factors are type of footwear, environmental conditions and physical activity.

Prevalence of flat foot among age groups from 6yrs to 10yrs is 26.35% to 11.19% were recorded. Vergera had reported diminished prevalence of flat foot in children over 6 yrs of age and suggested that the therapeutic measures before this age are not recommended [33,42].

In addition Gracia had stated the critical age for development of the plantar arch is 6yrs and consequently, if the prevalence of flat feet is evaluated before this age the finding will overestimate the problem. Therefore here 6 to 10 aged children were selected for the study[23, 42].

Flat feet is often a complex disorder in which MLA is collapsed/flatted or depressed sole of the foot comes in contact with ground. In flat feet the progressive weight bearing/stress produced calcanialvalgacity or flattened arches to drift or four feet abduction, pronated or everted foot. The head of the talus is no more supported and the body weight forces it downward and medially between the calcanial and navicular. And the flat feet patient body weight is not uniformly distributed due to which there is an abnormal stress on the joints of the foot, knee, pelvic, and also produce the excessive stress on the joint. If a flat foot is not treated progressive stress will permanently stretch the ligament/tendons and abnormally change the shape of devolving bone. Ultimately diverse symptoms and varying degree of disability and deformity will occur.[7,23,41]

Flat foot signs and symptoms:

Most common signs and symptom of the flat foot are:

1. Pain in the foot, knee, ankle, pelvis, hip, lower back.
2. Stiffness of the joint
3. Sign of tiredness and fatigue on prolonged walking and over standing
4. Flattened MLA on standing
5. Pronated foot
6. Difficulty wearing shoe
7. Shoes having uneven sole due to increase pressure on medial side of the sole of the foot.[1,2,5]

The treatment for the flat foot the biomechanics of the normal arch, rebalancing the forces that act on the arch can improve the function and lessen the chance for further or subsequent development of the deformity[42]. Hence these are all the primary focus of occupational therapy intervention in paediatric functional areas.

The use of 3D surface scanning technologies to produce digitalized representations of parts of the human anatomy has the potential help to change the way a wide range of products are designed and fabricated[40].

3D surface scanning has the potential to play an important role in the development of customised products, i.e. devices and apparel that are designed for the individual using their precise anthropometric measurements.[37]

OPERATIONAL DEFINITION

Flat foot: Absence of an arch in the sole of the foot that causes the foot to lie flat when the person is standing.

Heel valgus: Eversion and abducted rear foot is denoted as heel valgus.

Navicular height: It is the height measured as the perpendicular distance between the supporting surface and the most anterior inferior part of navicular tuberosity.

Insole: A device placed on the insole of the shoes/footwear to maintain arch support.

Medial Arch: The medial longitudinal arch is a concave arch that is located on the medial aspect of the foot between the head of the first metatarsal and the calcaneal tuberosity.

Voxel care online CAD CAM system (3D foot scanner): Voxel care orthotic CAD is an easy to use and powerful tool to design any type of orthotic insole. It is a scanner system.

Voxelcare VCM70 Orthotic CNC Milling Machine: The Voxelcare VCM70 Orthotic CNC Milling Machine is a high-end 1 pair production model where performance in power as well as accuracy is required.

CONCEPTUAL DEFINITION:

Flat foot: Absence of an arch in the sole of the foot that causes the foot to lie flat when the person is standing this leads to problem in daily activities.

Heel valgus: Eversion and abducted rear foot is denoted as heel valgus, which is used to confirm the flat foot in children.

Navicular height: It is the height measured as the perpendicular distance between the supporting surface and the most anterior inferior part of navicular tuberosity, in children with flat foot the navicular height is reduced which indicates the medial longitudinal arch collapse.

Insole: A new technology designed and fabricated customised device placed on the shoes/footwear to maintain arch support, in children with flat foot.

Voxel care online CAD CAM system (3D foot scanner):

Voxel care orthotic CAD is an easy to use and powerful tool to design any type of orthotic insole. It is a scanner system used in this study for scanning the foot and to record the foot prints in the software to analyse while fabricating the customised insole for children with flat foot.

Voxelcare VCM70 Orthotic CNC Milling Machine:

The Voxelcare VCM70 Orthotic CNC Milling Machine is a high-end 1 pair production model used for making new technology insole for children with flat foot.

KEY WORDS:

Flat foot, Heel Valgus, Navicular Height, Insole, Medial arch, Voxel care 3D scanner, Voxel care milling machine.

NEED FOR THE STUDY

Majority of the children visiting occupational therapy clinics are delayed developmental children, many children with flat foot have developmental problems related to walking, jumping, stair climbing and backward walking and playing. These are the essential activities of daily living and feet play an important role in supporting the body and maintaining balance during mobility.

A flatfooted child with walking induces excessive foot pronation, which transfers the weight load to the tibia causing pain in the tibia and the knee. Most of the children have functional mobility issues due to flat foot. Hence in our present study we want to address this issue of flat foot with advanced foot insole technology.

Aim of the study:

The aim of the study is to find out the effectiveness of 3D foot scanner designed and fabricated customized foot insole in the management of children with flat foot.

Objective:

1. To identify the children with flat foot of 6 to 10yrs of age by using screening tool.
2. To assess the biomechanics of flat foot by using podiatry assessment
3. To evaluate the effectiveness of 3D foot scanner designed and fabricated customized foot insole in the management of children with flat foot by using Foot Function Index short form (FFI) and Oxford Ankle Foot Questionnaire – Parent version.

HYPOTHESIS

Null Hypothesis:

Effect of 3D foot scanner designed customized foot insole will have no significant effect in the management of flat foot.

Alternate Hypothesis:

Effect of 3D foot scanner designed customized foot insole will have significant effect in the management of flat foot.

SIGNIFICANCE OF THE STUDY

Much research evidence is seen in the treatment of congenital and acquired flatfoot using orthotics and proper insoles that reduce muscle activity, provide comfort, and increase exercise ability.

In our study we are using VOXEL Care online CAD CAM system which produces a 3D representation of its shape that can be viewed and analysed on a computer. The Software programs which allow these 3D models to be used as the basis for creation of foot insole design and integrated with computer controlled manufacturing systems which will produce the customized foot insole. Later these insoles fitted to the footwear or shoes for mobility. This insole supports a balanced weight distribution in the plantar area and arch, and aids in efficient shock absorption, including the ground reaction generated during walking or running, thus reducing pain and unstable joint motion.

This new technology has limited application in India. Hence, we want to introduce this technology to the children with flat foot and benefited by its use extensively.

Background of Foot

Our feet are incredibly specialized structure. It is the base of the body it acts like a foundation of building. It is unique structure composed of bones supported by muscles with tendons and ligaments arranged in unique form.

Anatomy of foot

Foot is divided into three parts mainly, hind foot -calcanious, talus, along with chopart line between calcanious/talus and cuneiform /cuboid, mid foot - navicular, cuboids, three cuneiforms with Lisfranc joint between tarsal and metatarsal bone and fore foot - five metatarsals and fourteen phalanges.[3]

Figure 1. Figure shows Anatomy of foot

Function of the foot

The foot support the body weight and provide the leverage for walking and running segments which enable to adopt the shape on un even surfaces. Foot has a dual function, first it act as a soft pad for stress absorption and secondly it act as a rigid organ during toe off phase of gait. Both feet bear 100% body weight (50% on each foot), 20% at heel, 17% at head of first metatarsal and 13% at head of fifth metatarsal. 1.2: Arches of Foot.

Arch is a segmental elevation of the foot. Human foot consist of 3 arches

1. Medial longitudinal arch (MLA)

2. Lateral longitudinal arch (LLA)

3. Transverse arch

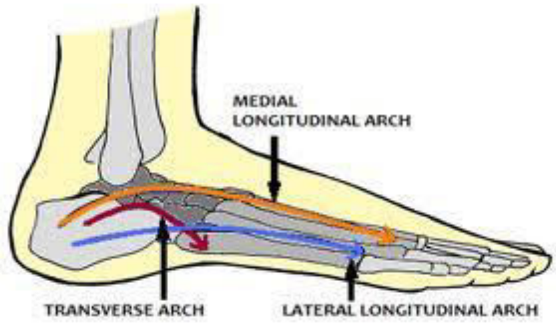


Figure 2. Figure shows Arches of the foot

Arches of the foot are supported by wedge shape bones, ligament and muscles with tendons of the foot and leg. Medial longitudinal arch and lateral longitudinal arch run anterio-posterior of the foot. Medial longitudinal arch consist of talus, calcaneum, navicular, 3 cuneiforms (medial, intermediate, lateral), 1st three metatarsals, tendons of tibialis posterior and anterior muscles include (plantar aponeurosis, abductor hallucis, flexor hallucis longus, flexor hallucis brevis, medial part of flexor hallucis longus). Ligaments (plantar calcanionavicular or spring ligament, deltoid ligament). Medial longitudinal arch is clinically more important than other arches. Main feature of MLA is its elasticity and height (15-18mm), lateral longitudinal arch (LLA) consist of calcaneum, cuboid, 4th and 5th metatarsals, muscles, ligaments (long plantar, calcaneocuboid ligament) LLA is solid and slightly elevated. Transverse arch consist of 5 metatarsal, cuboid. When there is an excessive stress on the supporting structure of the arches due to prolong walking, standing or overweight as a result of which arches may collapse and produce complications.[1]

Biomechanics of Medial longitudinal arch

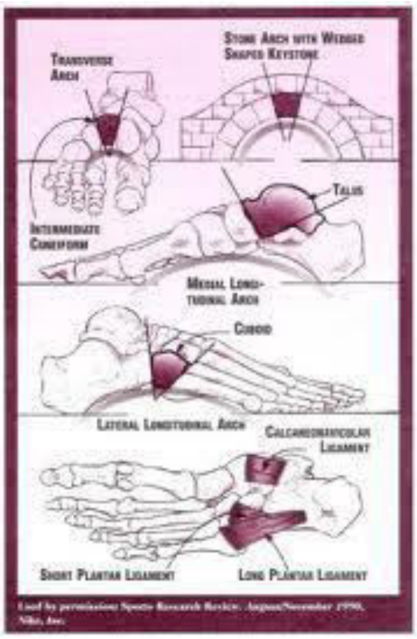


Figure 3. Figure shows biomechanics of the foot

When we describe the medial longitudinal arch biomechanically it is just like a suspension bridge. Shape of the bone is like the stones of the bridge in which the sustenticulumtali hold up the talus, concave proximal surface to the navicular bone receive rounded head of the talus which is the key stone of the bridge (as shown in figure) in the center of the arch the inferior edge of the bones are tight together by stronger plantar ligament for example strong plantar ligament calcanionavicular ligament or spring ligament and fan like extension of insertion of posterior tibialis tendon. The end of the arch is tight by the plantar aponeurosis, medial part of flexor digitorum brevis, abductor hallucis, flexor hallucis longus, medial part of flexor digitorum longus, flexor digitorum brevis. From the above the arch is suspended by tibialis anterior and medial ligament of ankle joint deltoid ligament.[3]

Flat Feet, Pes Planus, Pronated Feet

Flat feet is often a complex disorder in which MLA is collapsed/ flatted or depressed sole of the foot comes in contact with ground. In flat feet the progressive weight bearing/stress produced calcanialvalgacity or flattened arches to drift or fore feet abduction, pronated or everted foot. The head of the talus is no more supported and the body weight forces it downward and medially between the calcanial and navicular. The flat footed individuals body weight is not uniformly distributed due to which there is an abnormal and excessive stress on the joint of the foot, knee, pelvic. If the flat foot is not treated, progressive stress will permanently stretch the ligament and tendons leads to abnormal change in the shape of developing bone. Ultimately diverse symptoms and varying degree of disability and deformity will occur.[2]

Types of flat foot

Types of flat foot is classify on the basis of age.

1) Pediatric flat foot (mainly congenital)

2) Adult flat foot (mainly acquired)

1. Pediatric flat foot is a condition occurs in children. It is mostly bilateral, involving both sides of the foot. Pediatric flat foot either symptomatic or asymptomatic while the majority of flat foot has asymptomatic condition. The pediatric flat foot may be flexible or rigid. Flexible flat foot arch is collapsed in standing (weight bearing) and MLA reappears in sitting position (non-weight bearing). Flexible flat foot is more common than rigid flat foot. Mostly

occur in children, adolescent and continues in the adulthood. It is usually bilateral and asymptomatic but as the age progresses due to increase stresses from malalignment and improper weight distribution on the foot the soft tissue of the foot stretched, inflammed or tear then flexible flat foot become symptomatic.

Figure 3. Figure showing flexible flat feet

2. Adult or acquired flat foot is secondary to some disease, injury, illness, unusual prolonged stress are due to aging process. It is more common in women's above 40 years of age (obesity, diabetes, arthritis), flat foot in pregnancy is due to increase elastin (elasticity), other causes include trauma, fracture of foot bones, posterior tibial tendon rupture, polio, malalignment due to genuvalgum etc.[2,5] In Rigid flat foot the MLA remains flattened in sitting (non-weight bearing) as well as in standing (weight bearing). It is more symptomatic and less asymptomatic.

Causes of the Flat Feet

Flat foot will occur when there is any abnormality in supporting structure of the MLA like bone ligament muscle/tendon. The causes may classify as congenital and acquired. Congenital problems are tarsal collation (abnormal connection between the tarsal bones), congenital vertical talus, accessory navicular, cerebral palsy, spina bifida, muscular dystrophy, ligament laxity (elardanlose syndrome). Acquired flat feet is due to trauma, fractures, posterior tibial tendon rupture, arthritis, genu valgum, metatarsus adductus, tibial torsion, pregnancy obesity diabetes, tight Achilles tendon age related wear and tear and posterior tibial tendon insufficiency.[2,5,7]

Sign & symptoms

Flexible flat foot is asymptomatic but in some cases with aging process and the rigid flat foot is symptomatic.

Most common sign & symptom of the flat foot are:

1. Pain in the foot, knee, ankle, pelvis, hip, lower back pain
2. Stiffness of the joint (restricted movements)
3. Sign of tiredness & fatigue on prolonged walking and over standing
4. Flattened MLA on standing
5. Pronated foot
6. Difficulty in shoe wearing
7. Shoes having uneven sole due to increase pressure on medial side of the sole of the foot[5, 27]

Diagnosis of the flat foot

On the basis of visual inspections with special test, we made the diagnosis of flat foot. It is better to adopt stepwise approach for the diagnosis. It include subjective history, objective history, examination (look at the shape of the foot, shoes, bones, skin, muscles condition), feel for the tenderness symmetrically and move the foot actively and passively and analyse gait through OGA of the patient. Neuromuscular examination includes power, sensations, reflexes, vascular examinations which include pulses, temperature. After these examinations special tests are to be performed.[36]

1. Arch height on sitting and standing
2. Tip toe standing test (for rigid or flexible)
3. Single tip toe standing test (for tibialis posterior insufficiency)
4. Standing on heel (for tibialis anterior and contracture of Achilles tendon)
5. Great toe extension (normally elevation of MLA with lateral rotation of tibia)
6. Great toe malalignment
7. Foot prints (normally heel is oval and midline of the heel passes medial to the 2nd toe)
8. Valgus index (for medial or lateral shifting of the malleoli).draw a line from the mid of the heel to the mid of 3rd toe from the foot prints, then with the help of setsquare marks the position of the medial & lateral malleoli. Positive index show medial shifting & negative index shows lateral shifting[36]
9. Check the joint laxity (note passive hyperextension)
10. Length of calcanial tendon
11. Position of the patella
12. Navicular height[10,31,39]
13. X-ray for (bone connections), CT for (bony abnormalities & MRI for (soft tissues)[1,4,6]

14. 3D foot scanner and milling machine – Newer Technology which is used to assess and appears to be the most reliable method of obtaining anthropometric measurements.[37]

Gait cycle

Gait cycle consist of stance phase (60% of total gait cycle), in this phase the foot is in contact with ground. The other phase is swing phase (40% of total gait cycle),in this phase the foot is off the ground. The stance phase is divided into three phases, heel strike, mid stance and toe off. During stance phase foot has dual function. One is it serves as a soft organ at heel strike for stress/shock absorption. Another is at the mid stance(weight acceptance phase) the supination of mid tarsal joint convert the foot from soft organ to rigid organ which provide rigid lever arm for toe off phase.[1,2]

Gait cycle flat feet

A person with or without flatfeet at heel strike the ground, foot is pronated outward and there is inward rolling of the ankle. At the midstance phase the metatarsus joint supinates as a result, elevation of medial longitudinal arch and foot changes from soft to rigid organ while in case of flatfoot at heel strike along with normal pronation there is excessive inward rolling of the ankle, at the midstance phase while the midtarsal joint supinates and medial longitudinal arch comes in contact with the ground. The flatfeet person unable to toe off until he will unlock the midtarsal joint, for this purpose he will pronate the foot as a result the foot is again changes from rigid to flexible organ and there is excessive pressure on the medial aspect of the foot.[1,2]

Complications of Flatfoot:

Excessive inward rolling with pronated foot at midstance will lead to inward rolling of the knee as a result uneven weight or pressure distribution on the foot especially more pressure on the medial aspect on the foot, there is malalignment on the lower limb weight, pressure, malalignment exert abnormal stresses on the joint of the foot, knee, hip and lowerback, which makes the joint hyper mobile and unstable than it leads to stretching of the supporting tissue of the joint, later on other complications will produce like (hammertoes, plantar fasciitis, arthritic changes in foot, knee, hip and backache, shin,Achilles tendinitis, posterior tibial tendinitis, bunions[4,5,36]

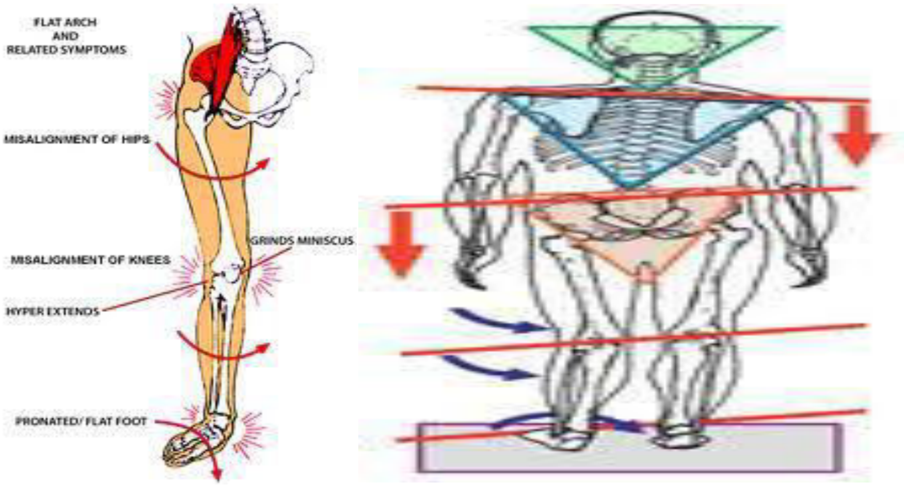


Figure 4. Figures showing complications of flat foot

Treatment Options of the Flatfoot:

Before starting the treatment of the flatfeet, properly diagnose the flatfeet especially the type of the flatfoot (either flexible/ rigid, symptomatic/ asymptomatic, congenital/ acquired). Different types of flatfoot require different types of treatment. Most of the cases conservative treatment is effective but in some cases nonconservative or surgical treatment is essential to get relief from the symptoms or to correct the deformity, in case of acquired flatfoot it is important to treat a cause, illness or disease which causes the flatfoot.

The treatment option for flatfoot includes:

1. Activity Modification: Cut down the activities that cause the pain and avoid prolong standing/walking to give rest to the arches with the arch support.

2. Proper Footwear: Proper shoe size and shoes with arch support are critical for developing bones because the bones are soft and malleable. Tight constricting shoes will interfere with normal growth; it may leads to deformity so shoes with arch support are useful.[35]

3. Weight Loss: Putting too much weight on arches may aggravate the symptoms.[31]

4. Medication: NSAIDS or analgesics help to relief from the symptoms.

5. Conventional Orthotic Devices: Majority of the flatfoot resolve with exercise and proper foot wear in 3-6 year of child and orthotics are seldom need in the early years of growth if there is an excessive pronation seems to persist beyond the age 6 to 7 responding poorly to home care interventions, the custom made orthotics or arch support are appropriate. This corrective support will provide to encourage normal development and prevent future deformity, reduce abnormal kinetic chain stresses and stresses on the foot, knee, pelvis, spine by keeping the body normally aligned[11.17,18]

6. 3D Scanned and fabricated newer technology Orthotic devices:

3D surface scanning technologies to produce digitised presentations of parts of the human anatomy has the potential to help designing and fabricating insole appropriately matching with anthropometric measurements to treatment will prevent future deformity and encourage normal development.[27,29,30]

Surgery:

There are different surgical techniques for the flat foot. Main purpose of surgical procedure is to relieve the symptoms, improving the foot function, decrease pronation in stance phase to provide proper weight bearing and stability to the joint of the foot.

Some Surgical Techniques are:

1) Rear foot osteotomies (surgical cut of the bone). Mainly in this procedure the position of the heel is changed to supinated from pronated position. Wedge osteotomies procedures are important.

2) Medial column stabilization.

3) Tendon transfer. The reattachment of tendon at different suitable location for the stabilization of the MLA.

4) Tendon lengthening in case of Achilles tendon contracture.

5) Arthrodesis- (Fusion of two or more bones). Major one is triple arthrodesis is fusion of talocalcanial, talo- navicular, and calcaneo-cuboid, the fusions are held together by pins or casting to provide immobilization for 2 to 3 months.[6]

The selection of procedure is on the basis of extent of deformity, x-ray findings, age, activity level and the duration of the recovery period depend upon the type of specific procedure performed.[6,44,45]

Ali K Thabet et al "Dynamic 3D shape of the plantar surface of the foot using coded structure of light" – 2014.

They stated that the foot provides a crucial contribution to the balance and stability of the musculoskeletal system, and accurate foot measurements are important in applications such as designing custom insoles/footwear. In recent years, digitally acquired scans of the foot have gained popularity among clinicians and foot specialists. Commercially available foot scanners provide static 3D reconstructions of the foot, but due to their expensive nature, different research systems have investigated more cost-efficient solutions, a good summary of 3D foot scanning methods can be found in the work by Telfer et al.

Shih YF et al "Lower extremity kinematics in children with and without flexible flat foot" – 2012.

In this study, a high percentage of young children present with flatfeet. Although the percentage of those with flatfeet declines with age, about 15% of the population maintains a flat arch. A reduction in longitudinal arch height usually combines with excessive subtalar joint pronation and may be related to other musculoskeletal problems of the lower extremity kinetic chain. Hence this study is to describe and compare the lower extremity kinematics between children with normal arches and those with flexible flatfeet, with the intent of providing practical information for decision making when treating children with flexible flatfeet.

Vergara A.E et al "Prevalence of flat foot in school between 3 and 10 years" – 2012.

The study conducted for the prevalence of flat foot in school children between 3 and 10 years among 940 total children, 60% were from Bogoto and remaining from Barranguilla, they found that diminished prevalence of flat foot in children over 6yrs of age suggest that therapeutic measures before this age are not recommended.

Angela Mackenzie et al "A review of the evidence for non-surgical interventions for flexible pediatric flat foot" – 2012.

They stated in his study that the pediatric flat foot is a frequent presentation in clinical practice, a common concern to parents and continues to be debated within professional ranks. The available prevalence estimates are all limited by variable sampling, assessment measures and age groups and hence result in disparate findings (0.6-77.9%). Consistently, flat foot has been found to normally reduce with age. The normal findings of flat foot versus children's age estimates that approximately 45% of preschool children, and 15% of older children (average age 10 years) have flat feet. Few flexible flat feet have been found to be symptomatic. Joint hypermobility and increased weight or obesity may increase flat foot prevalence, independently of age. Most attempts at classification of flat foot morphology include the arch, heel position and foot flexibility. Usual assessment methods are footprint measures, X-rays and visual (scaled) observations. Contemporary management of the pediatric flat foot is directed algorithmically within this review, according to pain, age, flexibility; considering gender, weight, and joint hypermobility. When foot orthoses are indicated, inexpensive generic appliances will usually suffice. Customised foot orthoses should be reserved for children with foot pain and arthritis, for unusual morphology, or unresponsive cases. Surgery is rarely indicated for pediatric flat foot (unless rigid) and only at the failure of thorough conservative management. The assessment of the pediatric flatfoot needs to be considered with reference to the epidemiological findings, where there is consensus that pediatric flexible flat foot reduces with age and that most children are asymptomatic. Globally, there is need for a standard by which the pediatric flat foot is assessed classified and managed. Until then, assessment should utilize the available evidence-based management model, the p-FFP Future research needs to evaluate the pediatric flat foot from representative samples, of healthy and known disease-group children prospectively, and using validated assessment instruments. He concluded foot exercises along with proper shoes and footwear were warranted.

Mette kjaergaardNilson, et al "Classification of the height and flexibility of the medial longitudinal arch of the foot" – 2012.

They stated that the navicular height is an important indicator for denoting flat foot; among this study they framed a standard level of navicular height which is highly useful for assessing the level of flat foot and for the provision of orthotic devices.

Navicular height levels:

NH – less than 2.7 cm – Severely low arch

NH – 2.7 cm to 3.5 cm – Low arch

NH – 3.6 cm to 5.5 cm – Normal arch

NH – 5.6 cm to 6.4 cm - High arch

NH – more than 6.4 cm – Severely high arch

Elly Budiman-Mak, et al "A review of the foot function index and the foot function index – revised" -2010.

They reviewed in 1991; the Foot Function Index (FFI) was developed as a self-reporting measure that assesses multiple dimensions of foot function on the basis of patient-centered values. The FFI consists of 23/17 items divided into 3 subscales that quantify the impact of foot pathology on pain, disability, and activity limitation in patients with RA. The FFI was developed using the classical test theory (CTT) method. It has been found to have good reliability and validity and has had wide appeal to clinicians and research scientists. In the past 20 years, the FFI has been widely used by clinicians and investigators to measure pain and disability in various foot and ankle disorders and its use has expanded to involve children, adults, and older individuals. Furthermore, the FFI has been widely used in the study of various pathologies and treatments pertaining to foot and ankle problems such as congenital, acute and chronic diseases, injuries, and surgical corrections.

Scott Telfer and James Woodburn "3D surface scanning of the foot as an integral element" – 2010.

They explored in his study, modern 3D surface scanning systems can obtain accurate and repeatable digital representations of the foot shape and have been successfully used in medical, ergonomic and footwear development applications. Finally he was found that the potentiality of the use of 3D surface scanning technologies play an important role in the development of customised products, i.e. devices and apparel that are designed for the individual were using their precise anthropometric measurements.

Morris C, et al "The Oxford Ankle Foot Questionnaire for children" – 2009.

They designed, studied and found out the reliability and validity of The Oxford Ankle Foot Questionnaire for Children (OxAFQ-C), created A Guide to the Scoring System for child patients (aged 5-16) affected by foot and ankle conditions to measure issues that are considered important to children. The OxAFQ-C (Parent version) has a total of 15 items, 14 (the first 14 items) of which are used to calculate domain scores, the three domains are Physical (6 items, 1 - 6), School and Play (4 items, 7 - 10), Emotional (4 items, 11 - 14) and final item (15) reflect the child concern about can or cannot wear the footwear they prefer and reported as a single item.

Hawke F, et al "Custom made foot orthotics for the treatment of foot pain"–2008.

Hawke F, et al (2008) stated that, for a number of conditions, customised foot orthotics have been shown to be more effective at reducing pain and redistributing pressure than standard "off the shelf" orthotics. Traditionally, customised foot orthotics are fabricated by taking a plaster cast of the plantar surface of the patient's foot (the negative cast), making a positive plaster cast of the foot by filling the negative cast, and then moulding the orthotic around the positive cast to obtain a high quality fit. The positive cast can be altered either by removing or adding plaster to it so that, for example, the orthotic will take pressure away from certain areas of the foot or provide support to the arch.

Deborah Ann George, MS, PT, and Lindsay Elchert, MPT "the Influence of Foot Orthoses on the Function of a Child with Developmental Delay" – 2007.

They stated lead to improved function when used to control faulty foot biomechanics. Hence this case report described the influence of modified stabilizing foot splints (SFSs) on the function of a child with developmental delay with hypotonic of 19 month old girl and developmental delay due to hydrocephalus and congenital absence of the corpus callosum. Modified SFSs as intervention were created with the child's feet held in a subtalar neutral position. Five items from the Peabody Developmental Motor Scale II (rise to stand, standing, lowering, cruising, and stepping forward) were tracked over three weeks, under three conditions: with shoes and orthoses, shoes only, and barefoot. The improvement was recorded only when wearing shoes and orthoses. The outcome indicated that future study of the modified SFS as an intervention is warranted.

Zhao J, et al "Computerized girth determination for custom footwear manufacture" – 2007.

In this study they stated that good fitting footwear requires matching not just the linear dimensions of feet but their girths as well. Footwear fitters have been using manual measurements for a long time, but the development of computerized techniques and scanner technologies have now made automatic determination of different foot dimensions feasible. The resistance to using such computer measurements has been the lack of trust in the accuracy of the data. This paper proposes an approach to obtain the necessary girths of feet in order to customize footwear. The proposed approach attempts to simulate the manual measurement procedures, and its effectiveness is assessed through an experiment with 15 foot castings. The results show that the simulated measurements can be within 5 mm of the manual measurements if the measuring locations can be correctly identified. Linear regressions show that the differences between the manual measurements and the simulated measurements can be modeled with the addition of a systematic error term of less than 4 mm. The computerized acquisition of foot dimensions is a useful way forward for custom shoe manufacturers. They used the device called Foot girth Custom footwear3D scanning Anthropometry Custom fit.

De pmagalhaes E, et al, “The effect of foot orthosis in rheumatoid arthritis” – 2006.

In this study they stated that, the foot orthoses was effective in 36 patients with rheumatoid arthritis by using the foot function index (FFI). All the patients were evaluated 30, 90 and 180 days after the baseline visit. FFI values, daily time of wearing the orthoses and adverse effects were noted at each appointment. The Stanford Health Assessment Questionnaire (HAQ) was used at the initial visit to evaluate the influence of physical condition on FFI response. With the use of foot orthoses, FFI values decreased in all subscales (pain, disability and activity limitation). This reduction was noted in the first month and was maintained throughout the trial. Those using EVA (ethyl-vinyl acetate; n^28) orthoses presented results similar to those for the total group. Patients wearing made-to-measure orthoses (n^8) exhibited higher initial FFI values and worse evolution during the trial, significant for pain and disability but not for activity limitation. Minor adverse reactions were noted; none required interruption of treatment. He concluded that the foot orthoses were effective as an adjuvant in the management of rheumatoid foot. They significantly reduced pain, disability and activity limitation as measured by the FFI, with minor adverse effects.

Powell M, et al “Efficacy of custom foot orthotics in improving pain and functional status in children with Juvenile idiopathic arthritis” – 2005.

In his study they compared the clinical efficacy of custom foot orthotics, prefabricated" off-the-shelf" shoe inserts, and supportive athletic shoes worn alone, on reducing pain and improving function for children with juvenile idiopathic arthritis (JIA). Children with JIA and foot pain (n= 40) were randomized to 3 groups. 1 group of 15 children received custom - made semi rigid foot orthotics with shock absorbing posts, 2 group of 12 children received off-the-shelf flat neoprene shoe inserts and 3rd group of 13 children received supportive athletic shoes with a medial longitudinal arch. Hence this study concluded that custom made semi rigid foot orthotics shows more efficacies compared with other groups.

Luximon A and Goonetilleke RS "Foot shape modelling" – 2004.

Luximon and Goonetilleke have argued that the foot shape can be modelled using length, width Identifying bony landmarks on the foot using markers that show up on the 3D scan appears to be the most reliable method of obtaining accurate girth measurements and other foot parameters in the case of the foot, quantitative description of its shape is important for a number of different applications relating to the ergonomic design of footwear, foot orthotics and insoles otherwise in appropriate footwear is a major cause of foot illness among the children and elderly.

KyoChulSeo, PhD, et al "Impact of wearing a functional foot orthotic on ankle joint of frontal surface of young adults with flat foot" – 2004.

They stated in his study investigated the effects of proprietary foot orthotics in young adults with flatfoot to determine changes in the ankle joint angle in the coronal plane during the midstance phase. The subjects were 15 college students diagnosed with flatfoot. Changes in the ankle joint angle in the coronal plane in the midstance phase were measured using the Vicon Motion System before and after use of the orthotic. The data were analyzed using Statistical Package for the Social Sciences Win 16.0.The subjects showed significant increases in left and right ankle joint angles in the coronal plane during the midstance phase of the gait cycle after use of the orthotics. However, the difference between the left and right ankle joint angles showed no significant change, even though the difference increased after use of the orthotics. Young adults with flatfoot showed increased ankle joint angles after use of the orthotics. This suggests that orthotic footwear can shape the plantar arch and affect the ankle joint, and that constant use of orthotics would cause a dynamic change in normal walking.

Van Boerum DH1 and Sangeorzan BJ "Biomechanics and Pathophysiology of flat foot"- 2003

There are many terms to describe flat foot, some of the more common ones are pes planus, planovalgus, calcaneo valgus and fallen arches. The human foot has 26 bones, 10 major extrinsic tendons and their respective muscles, numerous intrinsic musculo tendinous units and more than 30 joints. These musculoskeletal structures work together with the neurovascular elements, fat pads and skin to provide a mobile sensate adaptive foundation during standing and to provide a means of balance and locomotion during gait. The flat foot describes the common end point of any abnormality that causes the medial longitudinal arch to collapse. Flat feet can cause severe symptoms or be asympomatic. Flat foot is now considered a normal variant assuming it functions in its normal capacity without symptoms. Children have developmental flat foot, has many causes and may be symptomatic or asymptomatic flexible or rigid. The cause may be abnormal bone and joint development like with a tarsal coalition a congenital vertical talus or an accessory navicular bone. Soft tissues of generalized ligamentous laxity from Marfan's or Ehlers Danlos can lead to a flat foot deformity. Adult flat foot may be categorized as either residual flat foot deformity from a developmental cause or as an acquired flat foot. Acquired flat foot is associated with a tight triceps surae or isolated gastronemous tightness, posterior tibial tendon dysfunction, midfoot laxity abduction of the forefoot, external rotation of the hindfoot subluxation of the talus traumatic deformities, ruptured plantar fascia, charcot's foot and neuromuscular imbalance (polio, cerebral palsy, closed head injury or following a cerebrovascular accident. It is difficult to define the exact cause of flat foot in every situation because of the multiple factors which can contribute to the deformity.

Angela M Evans, et al "Measuring the pediatric foot a criterion validity and reliability study of navicular height in 4 year old children" – 2003.

They stated in his study indicates that the use of navicular height as a clinical measure of the foot in 4yr old children among other parameters such as arch index, foot print analysis, rear foot angle and longitudinal arch angle. They determined the criterion validity and reliability of NH as a clinical foot measure in young children by using Sonography.

Garcia, R.A., et al "Flexible flat foot in children, a real problem? – 1999.

They had stated that the critical age for development of the plantar arch is 6 years, and consequently, if the prevalence of flat feet is evaluated before this age, the finding will overestimate the problem. Therefore, 6-10 aged children were selected as research subjects in the present study because that is the most appropriate age to investigate the intervention effectiveness.

Losito JM "Clinical Biomechanics of the lower extremity" – 1996.

He stated in his study about modern scanning systems allow the "positive" shape of the foot to be obtained directly, circumventing the need to cast the foot (although some handheld systems do allow a cast of the foot to be scanned. A number of software packages (for example Orthomodel from Delcam PLC, Birmingham, UK; and Automated Orthotic Manufacturing System, Sharp Shape, CA, USA) have been developed which have the ability to design foot orthotics based directly on the 3D representations of the foot obtained by surface scanning. The software, as well as matching the shape of the foot sole, allows the user to alter the shape and thickness of the orthotic in a controlled manner, giving greater design freedom than traditional plaster cast methods. By linking up with computer controlled milling or routing machines that can manufacture the orthotics, this approach reduces the number of steps in the process as well as removing many of the sources of human error.

Budiman-Mak E et al "The Foot Function Index" – 1991.

He designed a Questionnaire is called Foot Function Index (FFI). This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in everyday life. In this, totally 17 items, would like you to score each question on a scale from 0 (no pain or difficulty) to 10 (worst pain imaginable or so difficult it required help) that best describes your foot over the past WEEK. Reliability and Validity of the FFI: N = 87, with RA Test-retest reliability of FFI total and sub-scale scores: 0.87-0.69. Internal consistency: 0.96-0.73 Strong correlation between FFI total and sub-scale scores and clinical measures of foot pathology supported criterion validity of the index. Number of Items: 23/17 (short forms) 68 (long forms). http://www.proqolid.org/instruments/foot_function _index_ffi retrieved 02/08/2010.

RESEARCH DESIGN

Quasi Experimental study

SAMPLE SIZE:

The sample size for the study is 30 children:

- 15 Children in Control group
- 15 Children in Experimental group

SAMPLING TECHNIQUE:

Convenient sampling technique

VARIABLES UNDER STUDY:

Independent Variable – 3D designed and Fabricated Customised Insole

Dependent Variable – Children with flat foot.

LOCATION OF STUDY:

The Leprosy Mission Trust India, Community project (PARTI), Cuddalore district, Tamilnadu. (Early Intervention Centre at PARTI Project).

DURATION OF THE STUDY:

- Duration of the study is 1year
- Duration of intervention is Four months (September to December).

SCREENING CRITERIA:

Inclusion Criteria:

- Age – 6- 10 years
- Children with Flat foot
- Both Gender
- Bilateral involvement
- Children with normal cognition and communication skills

Exclusion Criteria:

- Recent fractures of lower limb
- Those who are not willing to wear foot wear.
- Acute inflammatory condition
- Plantar ulcers
- Plantar warts
- Foot Deformity

INSTRUMENTS USED:

1. Voxel care online CAD CAM system (3D foot scanner):

Voxel care orthotic CAD is an easy to use and powerful tool to design any type of orthotic insole. It is a scanner system used in this study for scanning the foot and to record the foot prints in the software to analyse while fabricating the customised insole for children with flat foot.[37,40,45]

2. Voxelcare VCM70 Orthotic CNC Milling Machine:

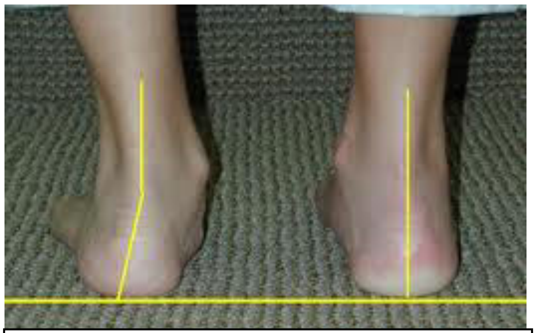
The Voxelcare VCM70 Orthotic CNC Milling Machine is a high-end 1 pair production model where performance in power as well as accuracy is required. Ideal for companies that want to start milling EVA orthotics in a clinical environment. Orthotics can be milled on 2-sides that will save a lot of manual finishing time and will give a consistent quality product. In the base unit the dust extraction unit and vacuum pump are integrated. The orthotic milling machine can be controlled from the supplied tablet as well as from a computer within the network.[9, 25]

TOOLS USED:

Tools used in this study is

1. **Podiatric assessment:** In Podiatric assessment, used to collect the information of biomechanics of foot in subtalar joint neutral position, after calcaneal bisection foot type of the children in standing position, Navicular height has been assessed.[5,7]

Foot Type:



Right foot shows rear foot neutral.

Left Foot shows rear foot valgus.

Figure 5. Figure shows calcaneal bisection

After calcaneal bisection, position the child is in standing, the examiner stands exactly behind the child and ask the child to march fast at the same spot for 3 to 4 times and then made to stand in erect posture. This is to stimulate walking and the joints of the foot will be in the correct positions (Subtalar joint neutral). Explain to the child to avoid turning back or bending down while doing the assessment and the examiner examines and categories the foot as being either supinated or pronated.

Criteria that satisfies the Pronatory and Supinatory foot type

Pronated:

- The heel will be in a valgus position (everted)
- There will be a bulge under the medial malleoli
- Achilis tendon may seem to be inserting more laterally.
- The medial arch will be flattened or reduced.
- The foot will probably be abducted (more than 2 toes can be seen lateral to the leg)

Supinated:

- The heel will be in varus position (inverted)
- There will be a slight bulge under lateral malleoli
- There will be a dip under the medial malleoli
- Achilis tendon seem to be medial
- High medial arch
- The foot may be adducted.

Navicular Height : In standing position, Navicular Height (H) was measured as the perpendicular distance between the supporting surface and the most anterior inferior part of navicular tuberosity.

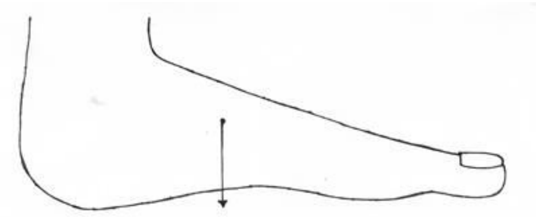
NH – less than 2.7 cm – Severely low arch

NH – 2.7 cm to 3.5 cm – Low arch

NH – 3.6 cm to 5.5 cm – Normal arch

NH – 5.6 cm to 6.4 cm - High arch

NH – more than 6.4 cm – Severely high arch 17.[31]



1. **Foot Function Index – Short form:**

This questionnaire has been designed to give your information as to how your foot pain has affected your ability to manage in everyday life. It contains 17 questions

Under this Questionnaire, we used to measure the impact of foot pathology of functions in terms of pain, disability and activity restriction on the basis of International classification of Function (ICF)

- Pain – (5items, 1-5)
- Mobility(Disability) – (9 items, 6-14)

- Activity Restriction – (3items, 15-17)

Scoring : High scores indicates greater the disability.

Reliability : Test-retest reliability of FFI of total and sub scores: 0.87 – 0.69

Validity : Internal consistency: 0.96-0.73[13,21]

1. **Oxford Ankle Foot – Questionnaire - Parent version**

The Oxford Ankle foot Questionnaire for Parent version is reported health status questionnaire is used for children aged from 5 – 16 years affected by foot and ankle conditions to measure issues that are considered important to children. The OxAFQ-C parent version has a total of 15 items, 14 (the first 14 items) of which are used to calculate domain scores, the three domains being:

- Physical (6 items, 1 - 6)
- School and Play (4 items, 7 - 10)
- Emotional (4 items, 11 - 14)
- The final item (item 15 – Has your foot or ankle stopped you wearing any shoes you wanted to wear?)

Scoring Methodology: Domain scores can be transformed to a percentage scale (0 – 100) to aid interpretation. A higher score for a domain represents better functioning.[32]

MATERIALS USED:

1. EVA (Ethylene Vinyl Acetate) sheet is used for making insole. The width of the EVA sheet is 35mm, in which the base is white in colour of 5mm height and

soreness, and the remaining upper sheet is black or brown in colour of 30mm height and soreness which helps in fabricating the stronger medial arch.

PROCEDURE FOR DATA COLLECTION:

A total of 30 Children with flat foot are selected in this study after their willingness to participate by undertaking informed consent. The sample selected based on the inclusion and exclusion criteria. Then the participants were divided into two groups randomly into control and experimental group with a sample size of 15 each.

Initially individual data for paediatric flat foot was done for control and experimental group using flat foot proforma, immediately to assess the biomechanics of flat foot among selected children using podiatry assessment manually, followed by the Tamil translated forms of Foot Function Index short form, Oxford ankle foot questionnaire- parent version data was collected for both the control and experimental group. Then 3D Foot scanner assessment was done for experimental group and the foot prints will be used for the designing and fabrication of customized foot insole. The parental group education programme conducted before the usage of insole.

Customized 3D foot analysed Foot insole produced by central fabricated by voxel care milling machine will be given to Experimental group children after the pretest data collection, the insole to be used by them after fixing on their footwear or shoes on regular basis of 8 hours of day timing for their functional activity. After a period of 4 months intervention post evaluation will be done to check the effectiveness of the foot insole.

During the initial intervention period children’s are advised to wear the insole for two hours continuously and then to remove it to check for any signs of inflammation. During entire intervention period regular monitoring the use of foot insole and safety of the children enquired through telephone communication and follow up house visits.

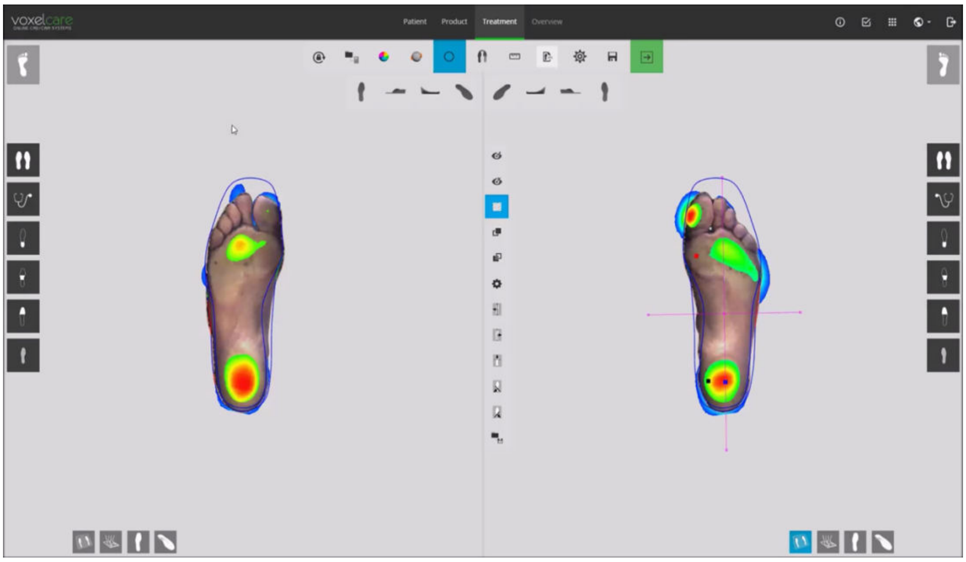
Whereas the control group children will not receive any special intervention for the foot apart from occupational therapy, during the study period and the initial assessments on the parameter will be measured and post evaluation will be done after a period of 4 months' time.

After this intervention, data's are tabulated and dealt with statistically treated with "t" test.

SAFETY PRECAUTIONS:

1. Should check the skin colour changes periodically.
2. Should keep the footwear inside the house to prevent from dog biting.
3. Should not wash the foot wear.
4. Should not wear the foot wear too tight or too loose.
5. During the initial period recommended to wear continuously for 2 hours then removing, checking and wearing it again.


voxelcare


voxelcare
Patient
Product
Treatment
Overview

DATA SHEET FOR EXPERIMENTAL AND CONTROL GROUP

S. NO	*IDENTITY CODING*	*AGE*	*SEX*	*NAVICULAR HEIGHT (in cms)*				*FFI PRE SCORE in %*	*FFI POST SCORE In %*	*OXFORD PARENT QUESTIONAIRE PRE SCORE*	*OXFORD PARENT QUESTIONAIRE POST SCORE*
				PRE RT FOOT	*POST RT FOOT*	*PRE LT FOOT*	*POST LT FOOT*				
1	*E1*	*6yrs*	*Fch*	*1.6*	*4.1*	*1.5*	*4.0*	*54*	*38*	*11*	*25*
2	*E2*	*7yrs*	*Mch*	*1.5*	*4.0*	*1.5*	*4.0*	*53*	*32*	*14*	*28*
3	*E3*	*7yrs*	*Mch*	*2.1*	*4.6*	*1.9*	*4.4*	*39*	*27*	*28*	*39*
4	*E4*	*6yrs*	*Mch*	*1.8*	*4.3*	*1.8*	*4.3*	*45*	*34*	*20*	*32*
5	*E5*	*8yrs*	*Mch*	*1.5*	*4.0*	*1.5*	*4.0*	*52*	*40*	*27*	*37*
6	*E6*	*10yrs*	*Mch*	*1.8*	*4.3*	*1.9*	*4.4*	*44*	*30*	*15*	*26*
7	*E7*	*6yrs*	*Mch*	*1.9*	*4.4*	*1.9*	*4.4*	*52*	*38*	*14*	*28*
8	*E8*	*7yrs*	*Fch*	*1.7*	*4.2*	*1.7*	*4.2*	*60*	*46*	*10*	*23*
9	*E9*	*10yrs*	*Mch*	*1.9*	*4.4*	*1.9*	*4.4*	*61*	*45*	*5*	*18*
10	*E10*	*10yrs*	*Mch*	*1.9*	*4.4*	*2.0*	*4.5*	*65*	*49*	*14*	*24*
11	*E11*	*8yrs*	*Mch*	*1.5*	*4.0*	*1.6*	*4.1*	*68*	*54*	*11*	*24*
12	*E12*	*6yrs*	*Fch*	*1.5*	*4.0*	*1.5*	*4.0*	*66*	*51*	*14*	*25*
13	*E13*	*10yrs*	*Fch*	*1.7*	*4.2*	*1.7*	*4.2*	*60*	*47*	*18*	*29*
14	*E14*	*10yrs*	*Mch*	*1.9*	*4.4*	*1.9*	*4.4*	*55*	*42*	*21*	*30*
15	*E15*	*8yrs*	*Mch*	*1.7*	*4.2*	*1.7*	*4.2*	*57*	*42*	*15*	*26*
16	*C1*	*6yrs*	*Mch*	*1.9*	*1.9*	*1.9*	*1.9*	*56*	*59*	*19*	*18*
17	*C2*	*6yrs*	*Fch*	*1.6*	*1.6*	*1.7*	*1.7*	*52*	*51*	*15*	*15*
18	*C3*	*7yrs*	*Fch*	*1.8*	*1.8*	*1.8*	*1.8*	*61*	*61*	*16*	*17*
19	*C4*	*7yrs*	*Mch*	*1.6*	*1.6*	*1.6*	*1.6*	*56*	*56*	*14*	*12*
20	*C5*	*6yrs*	*Mch*	*2.1*	*2.1*	*2.1*	*2.1*	*51*	*50*	*24*	*23*
21	*C6*	*10yrs*	*Mch*	*1.7*	*1.7*	*1.7*	*1.7*	*60*	*60*	*14*	*14*
22	*C7*	*7yrs*	*Fch*	*1.8*	*1.8*	*1.7*	*1.7*	*58*	*57*	*13*	*13*
23	*C8*	*6yrs*	*Mch*	*1.9*	*1.9*	*1.9*	*1.9*	*57*	*57*	*17*	*17*
24	*C9*	*7yrs*	*Fch*	*1.9*	*1.9*	*2.0*	*2.0*	*56*	*55*	*26*	*27*
25	*C10*	*9yrs*	*Mch*	*2.2*	*2.2*	*2.1*	*2.1*	*49*	*49*	*28*	*28*
26	*C11*	*8yrs*	*Mch*	*1.9*	*1.9*	*1.9*	*1.9*	*55*	*55*	*19*	*19*
27	*C12*	*8yrs*	*Mch*	*1.8*	*1.8*	*1.8*	*1.8*	*48*	*47*	*26*	*27*
28	*C13*	*6yrs*	*Mch*	*1.5*	*1.5*	*1.5*	*1.5*	*71*	*71*	*13*	*13*
29	*C14*	*7yrs*	*Fch*	*1.7*	*1.7*	*1.7*	*1.7*	*53*	*52*	*19*	*20*
30	*C15*	*6yrs*	*Mch*	*1.6*	*1.6*	*1.7*	*1.7*	*57*	*57*	*18*	*18*

TABLE-1

COMPARISON OF FOOT FUNCTION INDEX OF PRE TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

S.No	Foot Function Index	Mean	SD	t- Value	P- Value
1	Pre test – Control Group	56.00	5.58	0.231	P>0.05
2	Pre-test- Experimental Group	55.40	8.36		

Table 1, shows the Pre -test comparison between the control and experimental group for the Foot Function Index. The independent t test is used to compute the data of both the groups. The control group pre-test mean value 56.00 and Experimental group pre-test mean values 55.40 and t value is 0.231, P>0.05. Hence, there is no significant difference between the groups for the pre-test scores for Foot Function Index.

GRAPH-1

COMPARISON OF FOOT FUNCTION INDEX OF PRE TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

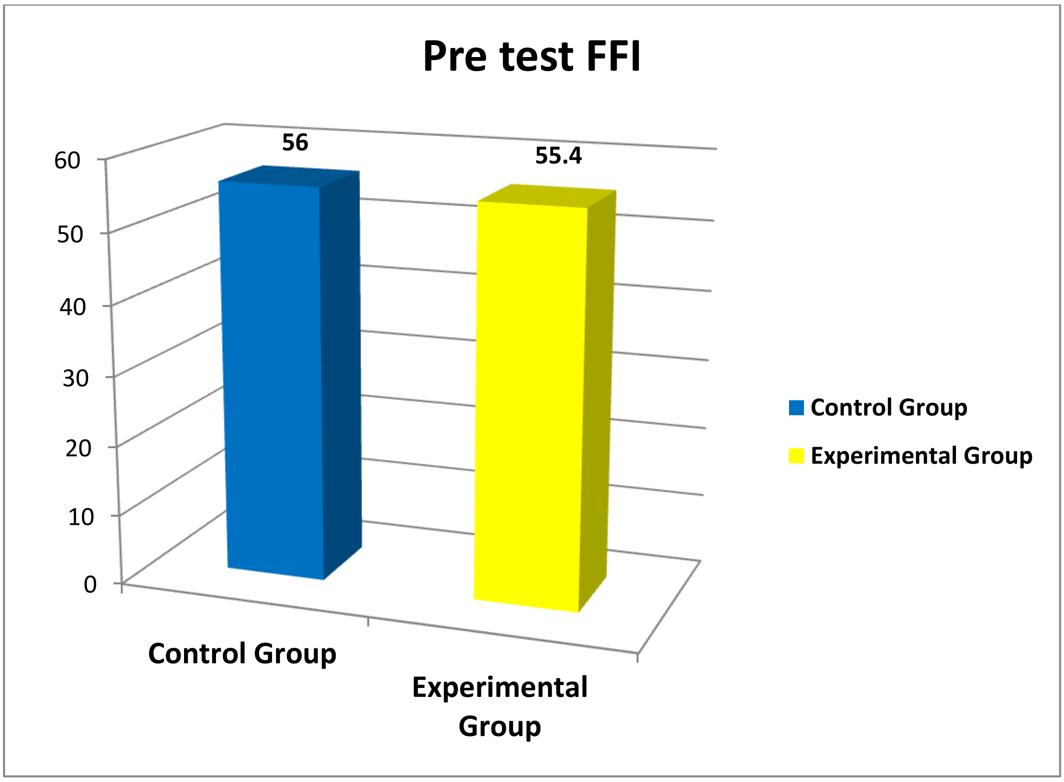


TABLE-2

COMPARISON OF OXFORD ANKLE FOOT QUESTIONNAIRE PRE TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

S.No	Oxford Ankle foot Questionnaire	Mean	SD	t- Value	P- Value
1	Pre- test – Control Group	18.73	5.04	1.425	P>0.05
2	Pre-test- Experimental Group	15.80	6.18		

Table 2, Shows the Pre -test comparison between the control and experimental group for the Oxford Ankle foot Questionnaire. The independent t test is used to compute the data of both the groups. The control group pre-test mean value18.73 and Experimental group pre-test mean values 15.80 and t value is 1.425, P>0.05. Hence, there is no significant difference between the groups for the pre-test scores for Oxford Ankle foot Questionnaire.

GRAPH-2

COMPARISON OF OXFORD ANKLE FOOT QUESTIONNAIREPRE TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

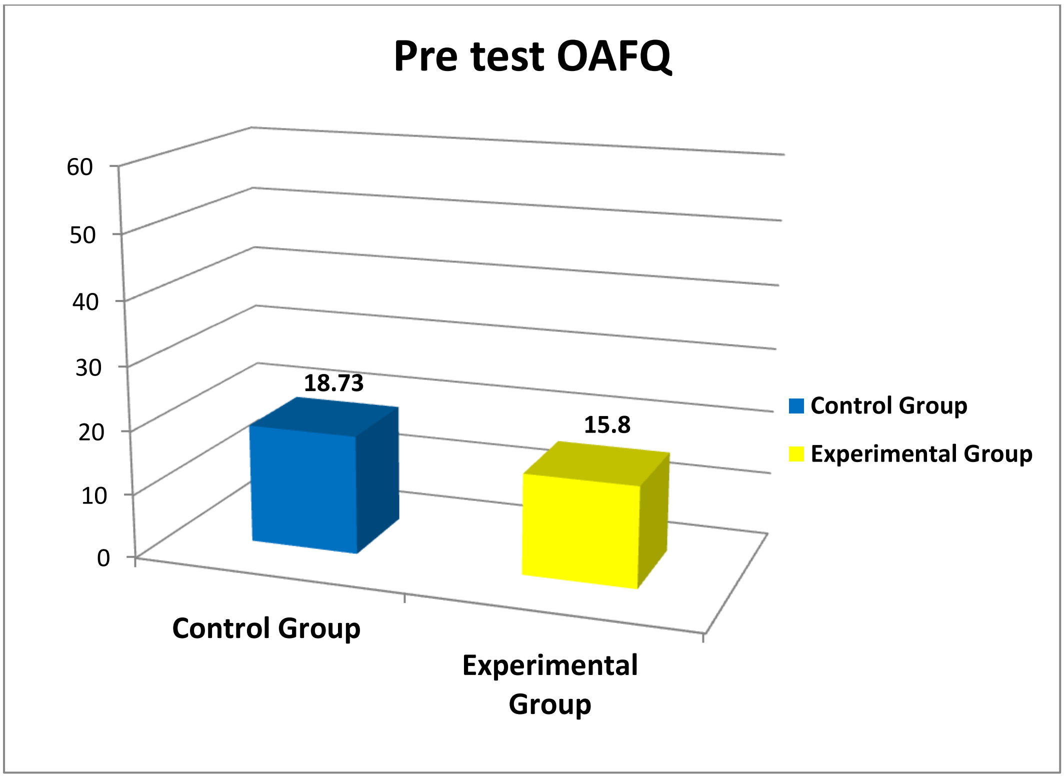


TABLE-3

COMPARISON OF FOOT FUNCTION INDEX BETWEEN PRE AND POST TEST OF CONTROL GROUP

S.No	Foot Function Index	Mean	SD	t- Value	P- Value
1	Pre- test – Control Group	56	5.58	0.763	P>0.05
2	Post-test- Control Group	55.80	5.89		

Table 3, Shows the Control Group comparison between pre-test and post test for Foot Function Index. The Paired t test is used to compute the data of both the control groups. The control group pre-test mean value56 and post-test mean values 55.80 and t value is 0.763, P>0.05. Hence, there is no significant difference between the pretest and post test of the control groups for Foot Function Index.

GRAPH-3

COMPARISON OF FOOT FUNCTION INDEX BETWEEN PRE AND POST TEST OF CONTROL GROUP

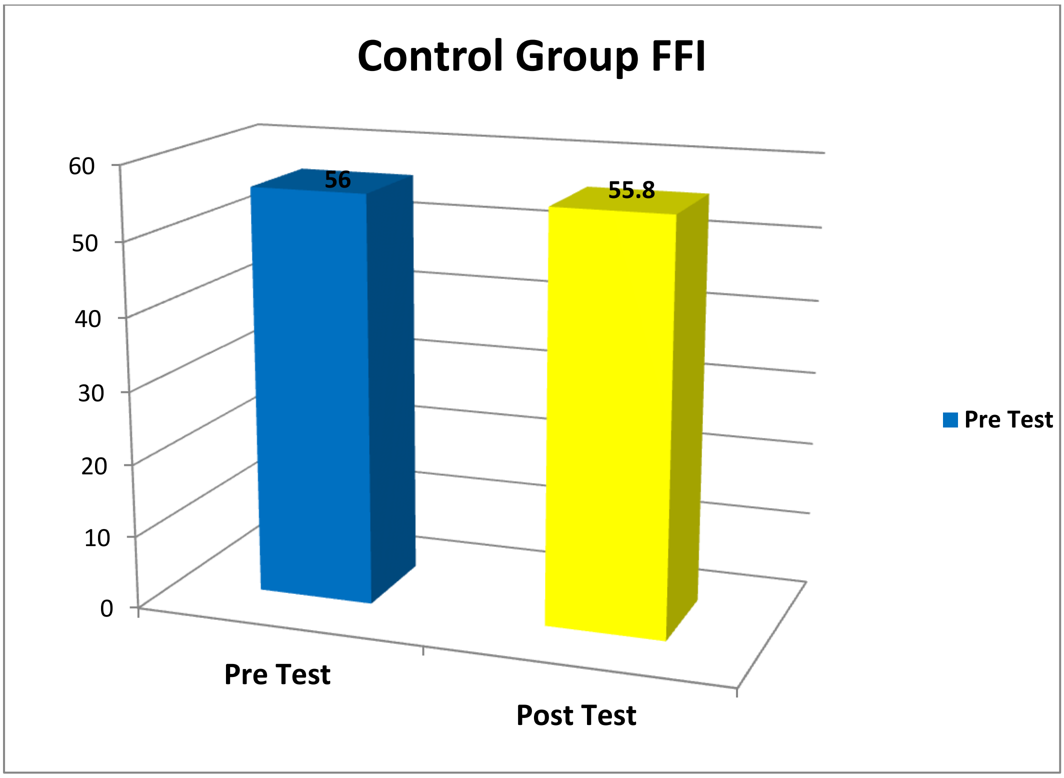


TABLE-4

COMPARISON OF OXFORD ANKLE AND FOOT QUESTIONNAIRE BETWEEN PRE AND POST TEST OF CONTROL GROUP

S.No	Oxford Ankle Foot Questionnaire	Mean	SD	t- Value	P- Value
1	Pre- test – Control Group	18.73	5.04	0.000	P>0.05
2	Post-test- Control Group	18.73	5.32		

Table 4, Shows the Control Group comparison between pre-test and post test for Oxford Ankle Foot Questionnaire. The Paired t test is used to compute the data of both the control groups. The control group pre-test mean value18.73 and post-test mean values 18.73 and t value is 0.000, P>0.05. Hence, there is no significant difference between the pretest and post test of the control groups for Oxford Ankle Foot Questionnaire.

GRAPH-4

COMPARISON OF OXFORD ANKLE AND FOOT QUESTIONNAIRE BETWEEN PRE AND POST TEST OF CONTROL GROUP

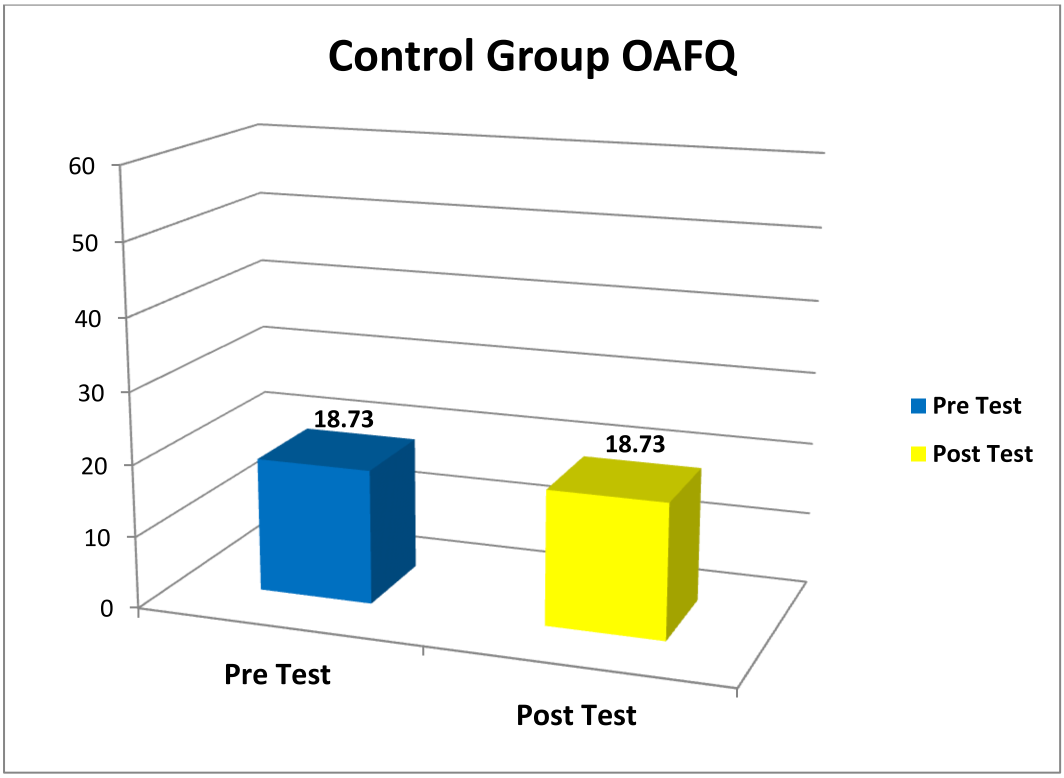


TABLE-5

COMPARISON OF FOOT FUNCTION INDEX BETWEEN PRE AND POST TEST OF EXPERIMENTAL GROUP

S.No	Foot Function Index	Mean	SD	t- Value	P- Value
1	Pre- test – Experimental Group	55.40	8.36	23.389	P<0.05
2	Post-test- Experimental Group	41.00	7.92		

Table 5, Shows the Experimental Group comparison between pre-test and post test for Foot Function Index. The Paired t test is used to compute the data of both the Experimentalgroups. The Experimental group pre-test mean value55.40 and post-test mean values 41.00 and t value is 23.389, P<0.05. Hence, there is Highly statistically significant difference between the pretest and post test of the Experimental Group for Foot Function Index.

GRAPH-5

COMPARISON OF FOOT FUNCTION INDEX BETWEEN PRE AND POST TEST OF EXPERIMENTAL GROUP

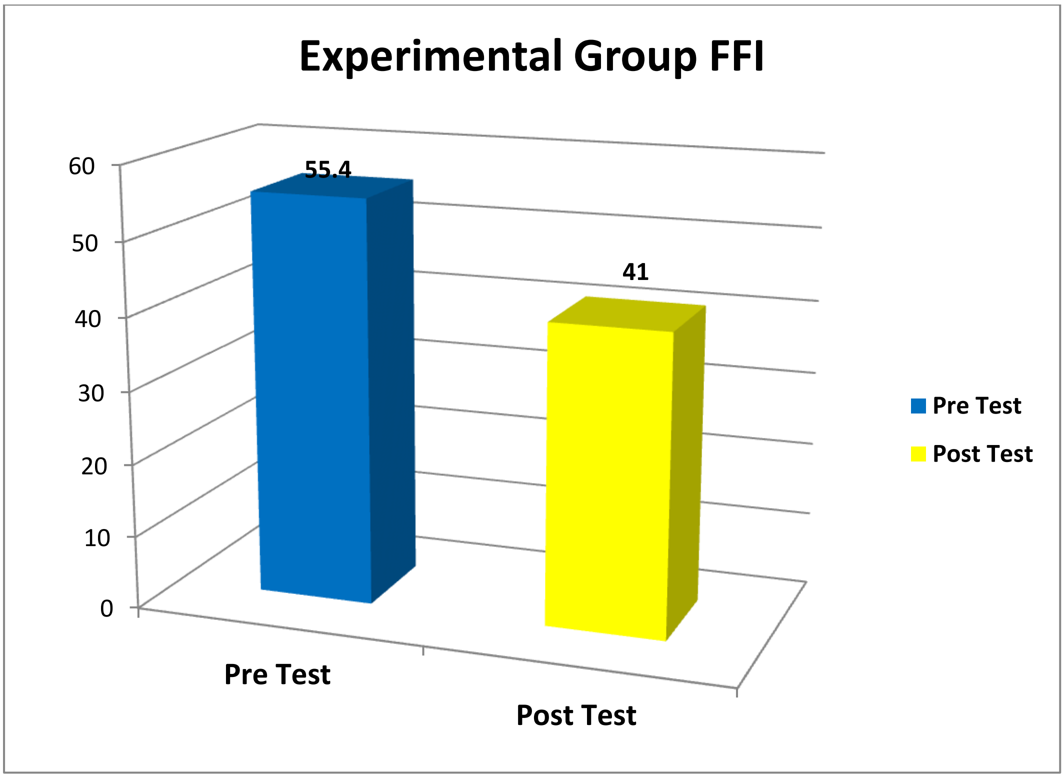


TABLE-6

COMPARISON OF OXFORD ANKLE AND FOOT QUESTIONNAIRE BETWEEN PRE AND POST TEST OF EXPERIMENTAL GROUP

S.No	Oxford Ankle Foot Questionnaire	Mean	SD	t- Value	P- Value
1	Pre- test – Experimental Group	15.80	6.18	28.342	P<0.05
2	Post-test- Experimental Group	27.60	5.37		

Table 6, Shows the Experimental Group comparison between pre-test and post test for Oxford Ankle Foot Questionnaire. The Paired t test is used to compute the data of both the Experimental groups. The Experimental group pre-test mean value15.80 and post-test mean values 27.60 and t value is 28.342, P<0.05. Hence, there is highly statistically significant difference between the pretest and post test of the Experimental groups for Oxford Ankle Foot Questionnaire.

GRAPH-6

COMPARISON OF OXFORD ANKLE AND FOOT QUESTIONNAIRE BETWEEN PRE AND POST TEST OF EXPERIMENTAL GROUP

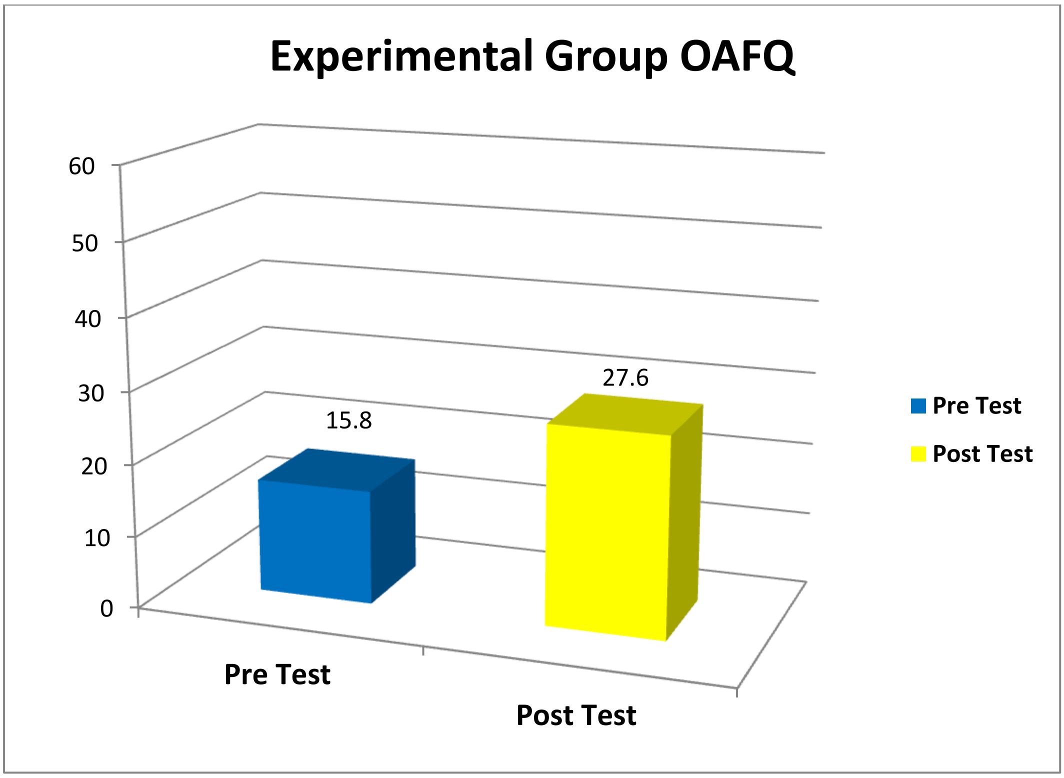


TABLE-7

COMPARISON OF FOOT FUNCTION INDEX OF POST TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

S.No	Foot Function Index	Mean	SD	t- Value	P- Value
1	Post-test – Control Group	55.80	5.89	5.8063	P<0.05
2	Post-test- Experimental Group	41.00	7.92		

Table 7, Shows the comparison between post test scores of Control Group and Experimental group for Foot Function Index. The independent t test is used to compute the data of both the post test of Control and Experimental groups. The Control group post-test mean value55.80 and Experimental group post-test mean values 41.00 and t value is 5.8063, P<0.05. Hence, there is highly statistically significant difference between the post test of the Control and Experimental Groups for Foot Function Index.

GRAPH-7

COMPARISON OF FOOT FUNCTION INDEX OF POST TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

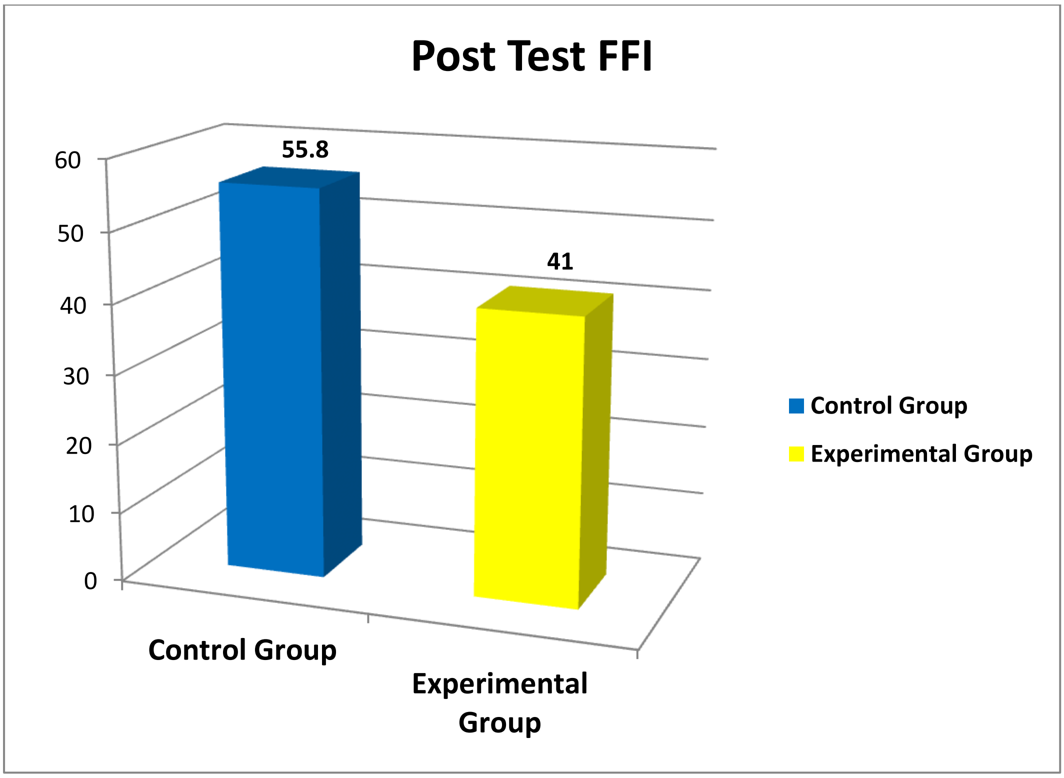


TABLE-8

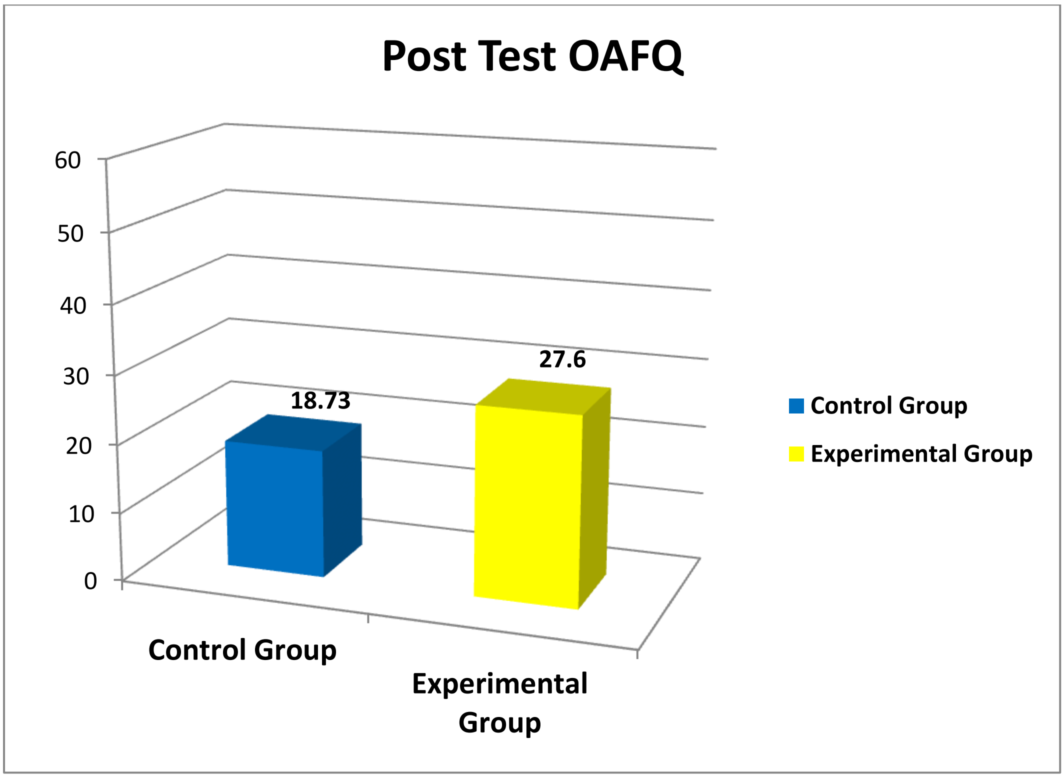
COMPARISON OF OXFORD ANKLE FOOT QUESTIONNAIRE POST TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP

S.No	Oxford Ankle Foot Questionnaire	Mean	SD	t- Value	P- Value
1	Post-test – Control Group	18.73	5.32	4.5413	P<0.05
2	Post-test- Experimental Group	27.60	5.37		

Table 8, Shows the comparison between post test scores of Control Group and Experimental group for Oxford Ankle Foot Questionnaire. The independent t test is used to compute the data of both the post test of Control and Experimental groups. The Control group post-test mean value18.73 and Experimental group post-test mean values 27.60 and t value is 4.5413, P<0.05. Hence, there is Highly statistically significant difference between the post test of the Control and Experimental Groups for Oxford Ankle Foot Questionnaire.

GRAPH-8

COMPARISON OF OXFORD ANKLE FOOT QUESTIONNAIRE POST TEST OF BOTH CONTROL AND EXPERIMENTAL GROUP



Flat foot causes abnormal stresses on the foot and lower extremity. The abductor hallucis is one of the important muscles that support the medial longitudinal arch. As flatfoot requires more work to do activities due to lack of medial longitudinal arch, the supporting muscles are fatigued due to excessive stress. The altered mechanical stresses on the structures can aggravate the foot deformity, there was evidence that flatfoot was positively associated with increased frontal plane motion of the rear foot. Hind foot eversion and forefoot abduction were much greater in the symptomatic population. Therefore flatfoot can cause problems related to body mechanics later in life. Shih YF et al – 2012. [23,38]

The consequences of flat foot can be prevented by early detection, correction and prevention. Both congenital and acquired flat foot can be corrected and prevented if early detection is done by parents and responsible health care professionals.

Many surface scanning systems available which can scan the plantar surface of the foot and leg. This produces 3D representation of its shape that can be viewed and analysed on a computer. Software programs which allow these 3D models to be used as the basis for shoe or foot orthotic design and integrate with computer controlled manufacturing systems are now widely available. This has meant that a number of footwear fabricators are now using integrated customisation systems to produce customer specific shoes and similarly there are now health care professionals providing customised foot orthotics that are based on scanning the patient’s foot shape.[14,22,25].

In this study 3D designed and customised fabricated insole arch support were given to improve the children flat foot, in which the medial arch of foot has been increased and maintained in children with flat foot from the mean navicular height of 1.73 cm and biomechanically the navicular height was increased at the mean value of 2.5cm. Total mean value of 4.23cm and rear foot become neutral in position (30). Total of 4 months intervention period, donning is the entire outdoor timing except for indoors and hygiene activities, especially eight hours in a day which was properly monitored in a separate log by the parent and therapist in the intervention centre. Initially individual data for paediatric flat foot was done for control and experimental group using flat foot proforma, followed by biomechanical assessment of flat foot among selected children were taken using podiatry assessment. Foot scanning procedure was done for experimental group by using Voxel care 3D foot scanner machine. Customized 3D foot analysed Foot insole produced by central fabricated by voxel care milling machine will be given to Experimental group. After the pre-test data collection parents are educated how to wear the insole and periodic interval of removing the insole during the intervention period. After 4 months of intervention period a post evaluation had done to check the effectiveness of the foot insole. During entire intervention period regular monitoring of the use of foot insole enquired through telephone communication and follow up house visits.

The pre-test and post-test were taken by Foot Function Index which shows the severity of pain, mobility and activity restriction due to flat foot and also evaluate the parental view of disability among their flat foot children by using Oxford Ankle Foot Questionnaire – Parent version. Both the Foot Function index form and Oxford Questionnaire was translated in to local language (Tamil). It was used during administration.

The comparison of Pre-test Foot function Index (FFI) for both control and experimental group (Table1, Graph 1) shows that Mean scores 56and 55.40 and

Independent t test value was 0.2313 and ($P > 0.5$), Hence there is no significant difference in the mean values for the FFI in both Groups.

The comparison of Pre-test Oxford Ankle foot questionnaire for both Control and experimental group (Table2, Graph 2) shows that Mean scores 18.73 and 15.80, Independent t test value was 1.4254 and ($P > 0.5$), Hence there is no significant difference in the mean values for the Oxford AFQ in both Groups.

The comparison of Foot function Index (FFI) for control group Pre-test and Post test (Table3, Graph 3) shows that Mean scores 56 and 55.80 and paired t test value was 0.7638 and ($P > 0.5$), Hence there is no significant difference in the mean values for the FFI in Control group for pre and post test.

The comparison of Oxford Ankle foot Questionnaire for control group Pre-test and Post test (Table4, Graph 4) shows that Mean scores 18.73 and 18.73 and paired t test value was 0.000 and ($P > 0.5$), Hence there is no significant difference in the mean values for the Oxford AFQ in Control group for pre and post test.

The comparison of Foot function Index (FFI) for Experimental group Pre-test and Post test (Table5, Graph 5) shows that Mean scores 55.40 and 41 and paired t test value was 23.3892 and ($P < 0.05$), Hence there is highly statistically significant difference in the mean values for the FFI in Experimental group. Hence, the Null hypothesis "Effect of 3D foot scanner designed customized foot insole will have no significant effect in the management of flat foot" was rejected. This is supported by the study done by **Scott Telfer and James Woodburn "3D surface scanning of the foot as an integral element" - 2010**[37] and found that the potentiality of the use of 3D surface scanning technologies play an important role in the development of customised products, i.e. devices and apparel that are designed for the individual were using their precise anthropometric measurements.

The comparison of Oxford Ankle foot questionnaire for Experimental group Pre-test and Post test (Table 6, Graph 6) shows that Mean scores 15.80 and 27.60 and paired t test value was 28.3427 and (P <0.05), Hence there is highly statistically significant difference in the mean values for the Oxford AFQ in Experimental group. Hence, the Null hypothesis “Effect of 3D foot scanner designed customized foot insole will have no significant effect in the management of flat foot” was rejected. The result is supported by **Hawke F, et al “Custom-made foot orthotics for the treatment of foot pain” -2008**[24] that, for a number of conditions, customised foot orthotics have been shown to be more effective at reducing pain and redistributing pressure than standard "off the shelf" orthotics.

The comparison of Post-test Foot function Index (FFI) for both experimental and control group (Table 7, Graph 7) shows that Mean scores 41 and 55.80, Independent t test value was 5.8063 and (P <0.05), Hence there is highly statistically significant difference in the mean values for the FFI in both Groups. This fairly suggests the effectiveness 3D foot scanner designed and fabricated customized foot insole used in the experimental group for the children with flat foot. **Losito JM – “Biomechanics of lower extremity impression casting techniques” – 1996**[27] **and Mauch M et al “A new approach to children’s footwear based on foot type classification” - 2009**[30] also found similar benefits in his study about modern scanning systems developed which have the ability to design foot orthotics based directly on the 3D representations of the foot obtained by surface scanning. The software, as well as matching the shape of the foot sole, allows the user to alter the shape and thickness of the orthotic in a controlled manner, giving greater design freedom than traditional plaster cast methods. By linking up with computer controlled milling or routing machines that can manufacture the orthotics, this approach reduces the number of steps in the process as well as removing many of the sources of human error.

The comparison of Post-test Oxford Ankle foot questionnaire for both experimental and control group (Table 8, Graph 8) shows that Mean scores 27.60 and 18.73, and independent t test value was 4.5413 and (P <0.05), Hence there is highly statistically significant difference in the mean values for the Oxford AFQ in both Groups. Hence3D foot scanner designed and fabricated customized foot insole used in the experimental group with flat foot showed effectiveness in wearing insole.

Present study has demonstrated that children in the experimental group who receives intervention of 3D designed and fabricated insole for maintaining arch support shows more statistical significant than the control group children. It is supported **by Leng J. du R**, **"A CAD approach for designing customised shoe last" - 2006**[27]. It is also validated by **De Mits S et al, "Validity and reliability of the infoot 3D foot digitizer for rheumatoid arthritis patients" - 2009**[20]**.** Hence the null hypothesis is rejected and accepting the alternative hypothesis. Thus the result supports a tentative conclusion that better Foot Function Index and improved parent perception about foot condition of the children with flat foot.

CONCLUSION

The result of this study indicates that children who underwent intervention of voxel care 3D fabricated insole as an orthotic device shows improvement in Foot function index and Oxford ankle foot questionnaire in comparison with control group children.

Hence I conclude that the new technology using 3D foot scanner designed and fabricated customized foot insole is effective in the management of children with flat foot.

LIMITATIONS:

- Study was done on a small sample size.
- Study was conducted for shorter duration.
- Gender comparison was not included in this study.
- Children only with pathological foot was selected others excluded.

RECOMMENDATIONS:

- The study can be done on a larger sample size.
- Study can be done on multiple locations
- Multiple factor analysis can be considered
- Various other treatment methods can be explored
- Long term follow up can be considered.

Books:

1. Essential of Orthopaedics and applied physiotherapy 2nd edition; 1999 Joshi, J. & Kotwal, P.
2. Joint Structure and Function – A comprehensive Analysis by Pamela K. Levangie, Cynthia C. Norkins.
3. Clinical anatomy by regions 8th edition 2008 by Snell, R. S.
4. Text book of Orthopedics by John Ebnezer and rakesh John 5th edition.
5. Text book of Podiatric Medicine by Catherine Hayer , Judith A. Barbara – Brown
6. Comprehensive Text book of Foot and Ankle Surgery – 4th edition by Joe T. southerland.
7. Illustrated Dictionary of Podiatry and Foot science by Jean Mooney forwarded by Steve west.
8. Pain – A text book for Health Professionals 2nd edition by Hubert Van Griensven, Jenny strong, Anita M. Unkuh.

Journals:

9. Ali K Thabet Email author, Emanuele Trucco, Joaquim Salvi, Weijie Wang and Rami J Abboud. Dynamic 3D shape of the plantar surface of the foot using coded structured light: a technical report.

10. Angela M Evans, Sheila D scutter, HalaIasiello, Measuring the paediatric foot a criterion validity and reliability study of navicular height in 4yr old children. The foot vol 13 issue 2 june 2003, pages 76 – 82.

11. Angela Mackenzie, Keith Rome, Angela Evans, A review of the evidence for non -surgical interventions for flexible pediatric flat feet. European physical rehabilitation med 2011 ; 47:1-2.

12. Borchers RB, Boone DA, Joseph AW, Smith DG, ReiberGB:numerical comparison of 3D shapes: potential for application to the insensate foot. J ProsthetOrthot 1995, 7:29-39.

13. Budiman-Mak E., Conrad, K. J., & Roach, K. E. (1991). The Foot Function Index: a measure of foot pain and disability. J ClinEpidemiol, 44(6):561-570.

14. Cheung J, Zhang M: Parametric design of pressure relieving foot orthosis using statistics-based finite element method, med Engphys 2008,30:269-277.

15. Conrad KJ, Budiman –Mak E, Roach KE, Hedeker D, Caraballada R, Burks D, Moore H. Impacts of footorthosis on pain and disability in rheumatoid arthritics. J. Clin Epidemiol.1996;49:1-7. Doi:10.1016/0895-4356(96)00534-3(pubmed) (cross ref)

16. D.Krupa Daniel *1, ChithambaramChandrasekaran 2, Ajith Mano 3. International Journal of Anatomy and Research, Int J Anat Res 2015, Vol 3(3):1240-44. ISSN 2321- 4287.

17. De pmagalhaes E, Davitt M, filho DJ, Battistella LR, Bertolo MB. The effect of foot orthosis in rheumatoid arthritis. Rheumatology (Oxford) 2006;45:449-453. Doi: 10.1093/rheumatology/kei163. (pubmed) (crossRef)

18. Deborah Ann George, MS, PT, and Lindsay Elchert, MPT. Deborah Ann George, MS, PT, and Lindsay Elchert, MPT Physical Therapy Program (D.A.G.), The University of Findlay; and Blanchard Valley Regional Health Center (L.E.), Findlay, Ohio (2007).

19. Deirdre Whitford, Ph.D.; Adrian Esterman, Ph.D. Whyalla Norrie, AustraliaA Randomized Controlled Trial of Two Types of In-Shoe Orthoses in Children with Flexible Excess Pronation of the Feet

20. De Mits S, coorevits P De Clercq D, Elewaut D, Woodburn J, Roosn P: validity and reliability of the infoot 3D foot digitizer for rheumatoid arthritis patients. Footwear Sci 2009, 1:101-103.

21. Elly Budiman-Mak, 1,2 Kendon J Conrad,3 Jessica Mazza,4 and A review of the foot function index and the foot function index – revised Rodney M Stuck5,6 The Oxford Ankle Foot Questionnaire for children: responsiveness and longitudinal validity.

22. Faustini MC, Neptune RR, Crawford RH, StanhopeSj: Manufacture of passive dynamic ankle foot orthoses using selective laser sintering. IEEE Trans Biomed Eng 2008, 55:784-790.

23. Garcia, R.A., Martin, J.F., Carnero, V.M., Gomez, A.J., Fernandez, C.J. Flexible Flatfoot in Children; a real problem? Pediatrics. 1999; 103(6):1-3.

24. Harris EJ. The natural history and pathophysiology of flexible flat foot. Clinical podiatry medical surgical 2010; 27:1-23.

25. Hawke F, Burns J, Radford JA, du Toit V. Custom-made foot orthotics for the treatment of foot pain. Cochrane Database Syst Rev. 2008;16:CD006801. [PubMed]

26. KyoChulSeo, PhD,1SeungHwan Park, PhD,2,* and KwangYong Park, MS3 . Impact of wearing a functional foot orthotic on the ankle joint angle of frontal surface of young adults with flatfoot

27. Leng J, du R: A CAD approach for designing customised shoe last. Computer Aided D appl 2006, 1:101-103.

28. Losito JM. In: Clinical Biomechanics of the lower extremity. Valmassy R, editor. St Louis; Mosby; 1996. Impression casting techniques.

29. Luximon A, Goonetilleke RS. Foot Shape Modeling. Hum Factors. 2004;46:304–315. doi: 10.1518/hfes.46.2.304.37346.

30. Mauch M, Grau S, Krauss I, Maiwald C, Horstmann T: A new approach to children’s footwear based on foot type classification. Ergonomics 2009,52:999-1008.

31. Mette kjaergaardNilson, RikkeFriis, Maria SkioldahlMichaelsen, Patrick Abildgaard, Rasmus Oestergaard Nielsen. Classification of the height and flexibility of the medial longitudinal arch of the foot.2012

32. Morris C, Doll H, Davies N, Wainwright A, Theologis T, Willett K, Fitzpatrick R. Qual. Life Res. (2009) 18:1367–1376.

33. Pfeiffer M, Kotz R, Ledl T, Hauser G, Sluga M: prevalence of flat foot in pre-school aged children.

34. Powell M, Seid M, szer IS. Efficacy of custom foot orthotics in improving pain and functional status in children with juvenile idiopathic arthritis: a randomized trial. J Rheumatol. 2005;32:943-950. (Pubmed).

35. Rao UB, Joseph B The influence of footwear on the prevalence of flat foot. A survey of 2300 children. J. of Foot and Ankle joint.

36. Rose GK, Welton EA, Marshall T The diagnosis of flat foot in the child. British medical journal flat foot in children,1990,301:1330_1

37. Scott Telfer and James Woodburn:3D surface scanning of the foot as an integral element. Journal of Foot and Ankle research 2010, 3:19

38. Shih YF, Chen CY, Chen WY, Lin HC. Lower extremity kinematics in children with and without flexible flatfoot: a comparative study. BMC Musculoskeletal Disord. 2012;13:31.

39. The optimal arch height for a patient with functional flat foot may depend on the goals of orthotic management. Studies suggest that arch height directly affects excessive motion, but that controlling dynamic balance may require a more tailored approach. By Stephen D. Perry, PhD, E. Anne Cunningham, Msc, CPaed, and Kelly M. Goodwin, BSc.

40. Treleaven P: Sizing us up – new 3 D body scanners are reshaping clothing car seats and more. IEEE Spectrum 2004, 41:17-19.

41. V. V. Senadheera [1]B. M. Nawagamuwa [1]K. Nidhya [1]S. Sivappriyan [1]W. M. S. M. Warnasooriya [1]P. M. Madhuranga [2]H. R. D. Peiris, Prevalence and associated factors of flat foot among 6 to 10 aged children in central province of Sri Lanka. Int J Physiother. Vol 3(3), 310-315, June (2016).

42. Van Boerum DH1, Sangeorzan BJ: Biomechanics and pathophysiology of flat foot. Foot Ankle Clin. 2003 Sep;8(3):419-30.

43. Vergara, A.E., Sanchez, R., Posada, J., Molano, A. Prevalence of flatfoot in school between 3 & 10 Years. Study of two different populations geographically and socially. Colomb Med. 2012; 43:141- 146.

44. Vincent.S. Mosca. Flexible flat foot in children and adolescents. J Child Ortho (2010) 4:107-121 DOI 10.1007/s11832-010-0239-9.

45. Volpon JB. Foot print analysis during the growth period. JPediatOrthoP. 1994;14:83-85.

46. Zhao J, Xiong S, Bu Y, Goonetilleke RS. Computerized girth determination for custom footwear manufacture. ComputInd Eng. 2008;54:359–373. doi: 10.1016/j.cie.2007.07.015.

Website:

47. www.pediatrics.orghttp://www.foothealthfacts.org/footankleinfo/pediatric-flatfoot.html

48. http://www.beiserpodiatry.com/common foot problems. htmlflat feet (Pes Planus) Dr.IanH.Beiser podiatry

49. www.north east footanklesurgery.co.uk/treatments/flat-foot

50. http://www.foothealthfacts.org/footankleinfo/pediatric-flatfoot.html

51. http://www.tenseconds.com/ffresearch.htm Flat Foot® Research by Dr. Pryce.

52. http://www.lowerextremityreview.com/article/orthotics-management-of-functional-flat-foot.

APPENDIX – I

PROFORMA OF FLAT FOOT

BIODATA :

NAME :

S/O :

AGE :

SEX :

DIAGNOSIS :

OCCUPATION OF THE CARE GIVER:

QUESTIONNAIRE:

1. Does the child has flat foot: yes/no
2. Family history of the flat foot: yes/no
3. Does the child has pain/tenderness: yes/no
4. Does the child feel fatigue on prolong standing: yes/no
5. Does the child has any other flat foot associated deformity: yes/no

   If yes: mention in detail:

EXAMINATION:

1. Does the child has flat foot: yes/no
2. Side of the foot involved: right/left
3. Arch on loading /weight bearing:

   Flattened/ semi flattened / arch maintained
4. Arch on unloading / non weight bearing

   Flattened / semi flattened / arch maintained

5. Toe standing test:

   Arch reappear / partially appear / arch remain collapsed

6. Foot print taken: yes/no

7. Type of the flat foot:

   Congenital / acquired

8. Flexible / rigid

9. Symptomatic / asymptomatic

10. Navicular height:

APPENDIX – II

PODIATRY ASSESSMENT

Hospital:
Registration No:

Date of assessment:
Assessment by:

Podiatry Assessment

(To be completed for all patients with plantar anaesthesia)

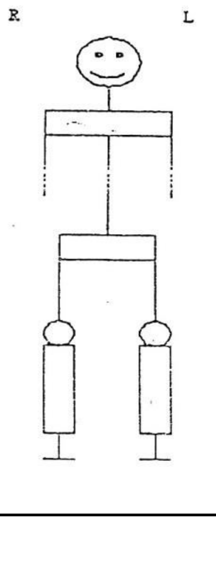
1. Joint examination

Assessment	Right foot			Left foot		
Ankle rom	*d/f*	≤10°	>10°	*d/f*	<10°	>10°
	p/f	≤20°	>20°	*p/f*	<10°	>20°
Subtalar rom	*inv'*	<4°	>4°	*inv'*	<4°	≥4°
	ev'	<6°	>6°	*ev'*	<6°	>6°
Midtarsal rom	low	medium	high	low	medium	high
1st ray rom	low	10°	high	low	10°	high
1st ray position	d/f	normal	p/f	d/f	normal	p/f
1st mtp rom	<60°		>60°	<60°		>60°

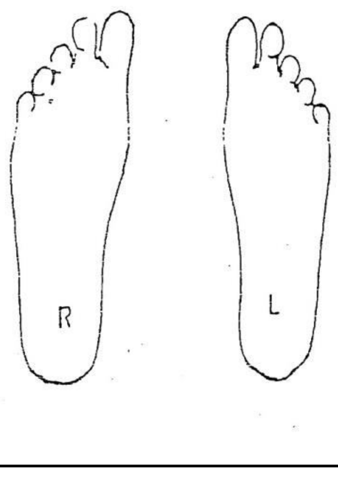
2. Functional examination

Assessment	Right foot				Left foot			
Rearfoot alignment	valgus	neutral	varus		valgus	neutral	varus	
Forefoot alignment	valgus	neutral	varus		valgus	neutral	varus	
FHL test	0	1	2	3	0	1	2	3
Footdrop	no	corrected	uncorrected		no	corrected	uncorrected	
Neuropathic Foot	no	partial	complete		no	partial	complete	
Foot-type	pronatory	normal	supinatory		pronatory	normal	supinatory	
Additional Comments								
Prescription								

Standing Examination



Plantar Lesion Patterns
& Subtalar Joint axis



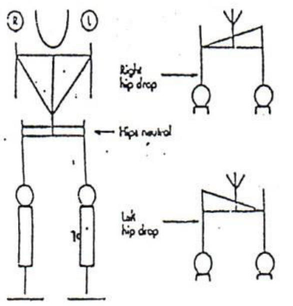
Hospital:
Registration No:

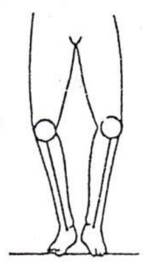
Date of assessment:
Assessment by:

Explanation of points in assessment sheet

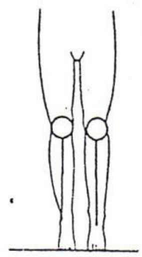
1. Joint examination		
Assessment		
	In the joint examination section, each joint is examined and a choice of options offered. One box only should be circled to highlight your choice. Abbreviations: D/F = dorsiflexion, P/F = plantarflexion Inv' = inversion, Ev' = eversion	
2. Functional examination		
Assessment		
	In the functional examination section, the same principles apply as to the joint exam. FHL test = Functional Hallux Limitus. Outcomes: 0 = no d/f present 1 = slight d/f present 2 = full range of d/f present 3 = full range of d/f + rearfoot supination Space has been left at the bottom of this column for any relevant additional points, and for the clinician to provide information on any intended intervention.	

Standing examination diagram:

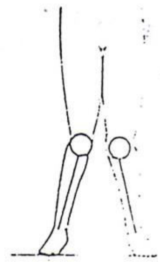




Genu Varum
Tibial Varum



Normal
Tibia Vertical



Genu Valgum
Tibial Valgum

Plantar Lesion Patterns:

Symbol	Meaning
⊗	Wound
≠≠≠≠≠	crack/fissure
©	corn/callus
Ⓢ.....	Scarring

Subtalar Joint Axial position is represented by a straight line being drawn from heel to toe.

Foot-type:

Rearfoot	Talar head palpation
	Curves above and below lateral malleoli.
	Inversion/eversion of the calcaneus
Forefoot	Bulge in the region of the TNJ
	Congruence of the medial longitudinal arch
	Abduction/adduction of the forefoot on the rear foot (too-many-toes).

APPENDIX – III

FOOT FUNCTION INDEX

Foot Function Index

Section 1: To be completed by patient   Name:________________________ Age:____ Date:________

Occupation:__________________________   Number of days of foot pain:_____________(this episode)

Section 2: To be completed by patient

This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in every day life. For the following questions, we would like you to score each question on a scale from 0 (no pain) to 10 (worst pain imaginable) that best describes your foot **over the past WEEK**. Please read each question and place a number from 0-10 in the corresponding box.

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Worst Pain Imaginable**

1.	In the morning upon taking your first step?	
2.	When walking?	
3.	When standing?	
4.	How is your pain at the end of the day?	
5.	How severe is your pain at its worst?	

Answer all of the following questions related to your pain and activities **over the past WEEK**, how much difficulty did you have? ***Disability Scale***

No Difficulty 0 1 2 3 4 5 6 7 8 9 10 ***So Difficult unable to do***

6.	When walking in the house?	
7.	When walking outside?	
8.	When walking four blocks?	
9.	When climbing stairs?	
10.	When descending stairs?	
11.	When standing tip toe?	
12.	When getting up from a chair?	
13.	When climbing curbs?	
14.	When running or fast walking?	

Answer all the following questions related to your pain and activities **over the past WEEK**. How much of the time did you: ***Disability Scale:***

None of the time 0 1 2 3 4 5 6 7 8 9 10 ***All of the time***

15.	Use an assistive device (cane, walker, crutches, etc) indoors?	
16.	Use an assistive device (cane, walker, crutches, etc) outdoors?	
17.	Limit physical activities?	

Section 3: To be completed by physical therapist/provider SCORE:_____/170 x100= _____% (SEM 5, MDC 7)

SCORE: Initial_____ Subsequent_____ Subsequent_____ Discharge_____

Number of treatment sessions:________________

Diagnosis/ICD-9 Code:______________________

[1] Adapted from Budiman-Mak E, Conrad KJ, Roach K. The foot function index: A measure of foot pain and disability. J Clin Epidemiology. 4(6): 561-70, 91.

APPENDIX – IV

OXFORD ANKLE FOOT QUESTIONNAIRE – PARENT VERSION

The questions below are based upon ways in which some young people told us they had been affected by a foot or ankle problem. We want you to think about each question and then put a tick or a cross next to the answer that best describes your child – was it never a problem for them, or was it always a problem, or was it somewhere in between?

Thinking about the last week…..

1. Has your child found walking difficult because of their foot or ankle?

never ○ rarely ○ sometimes ○ very often ○ always ○

2. Has your child found it difficult to run because of their foot or ankle?

never ○ rarely ○ sometimes ○ very often ○ always ○

3. Has it been difficult for your child to stand up for long periods?

never ○ rarely ○ sometimes ○ very often ○ always ○

4. Has your child had pain in their foot or ankle?

never ○ rarely ○ sometimes ○ very often ○ always ○

5. Have your child's legs been sore or ached after walking or running?

never ○ rarely ○ sometimes ○ very often ○ always ○

6. Has your child felt tired because of their foot or ankle?

never ○ rarely ○ sometimes ○ very often ○ always ○

7. Has your child's foot or ankle stopped them joining in with others in the playground?

never ○ rarely ○ sometimes ○ very often ○ always ○

8. Has your child's foot or ankle stopped them playing in the park or outside?

never ○ rarely ○ sometimes ○ very often ○ always ○

9. Has your child's foot or ankle stopped them taking part in PE lessons?

never ○ rarely ○ sometimes ○ very often ○ always ○

10. Has your child's foot or ankle stopped them taking part in any other lessons at school?

never ○ rarely ○ sometimes ○ very often ○ always ○

11. Has your child been bothered by how their foot or ankle looks?

never ○ rarely ○ sometimes ○ very often ○ always ○

12. Has the way your child walks bothered them?
never rarely sometimes very often always
13. Has your child been embarrassed because of their foot or ankle?
never rarely sometimes very often always
14. Has anyone been unkind to your child because of their foot or ankle?
never rarely sometimes very often always
15. Has your child's foot or ankle stopped them wearing any shoes they wanted to wear?
never rarely sometimes very often always

MASTER CHART FOR CONTROL GROUP

S.NO	IDENTITY CODING	AGE	SEX	NAVICULAR HEIGHT IN CMS.				FFI PRE SCORE In %	FFI POST SCORE In %	OXFORD PARENT QUESTION AIRE PRE SCORE	OXFORD PARENT QUESTIONAIR E POST SCORE
				PRE RT FOOT	POST RT FOOT	PRE LT FOOT	POST LT FOOT				
1	C1	6yrs	Mch	1.9	1.9	1.9	1.9	56	59	19	18
2	C2	6yrs	Fch	1.6	1.6	1.7	1.7	52	51	15	15
3	C3	7yrs	Fch	1.8	1.8	1.8	1.8	61	61	16	17
4	C4	7yrs	Mch	1.6	1.6	1.6	1.6	56	56	14	12
5	C5	6yrs	Mch	2.1	2.1	2.1	2.1	51	50	24	23
6	C6	10yrs	Mch	1.7	1.7	1.7	1.7	60	60	14	14
7	C7	7yrs	Fch	1.8	1.8	1.7	1.7	58	57	13	13
8	C8	6yrs	Mch	1.9	1.9	1.9	1.9	57	57	17	17
9	C9	7yrs	Fch	1.9	1.9	2.0	2.0	56	55	26	27
10	C10	9yrs	Mch	2.2	2.2	2.1	2.1	49	49	28	28
11	C11	8yrs	Mch	1.9	1.9	1.9	1.9	55	55	19	19
12	C12	8yrs	Mch	1.8	1.8	1.8	1.8	48	47	26	27
13	C13	6yrs	Mch	1.5	1.5	1.5	1.5	71	71	13	13
14	C14	7yrs	Fch	1.7	1.7	1.7	1.7	53	52	19	20
15	C15	6yrs	Mch	1.6	1.6	1.7	1.7	57	57	18	18

MASTER CHART FOR EXPERIMENTAL GROUP

S. NO	IDENTITY CODING	AGE	SEX	NAVICULAR HEIGHT IN CMS.				FFI PRE SCORE In %	FFI POST SCORE In %	OXFORD PARENT QUESTION AIRE PRE SCORE	OXFORD PARENT QUESTIONAIR E POST SCORE
				PRE RT FOOT	POST RT FOOT	PRE LT FOOT	POST LT FOOT				
1	E1	6yrs	Fch	1.6	4.1	1.5	4.0	54	38	11	25
2	E2	7yrs	Mch	1.5	4.0	1.5	4.0	53	32	14	28
3	E3	7yrs	Mch	2.1	4.6	1.9	4.4	39	27	28	39
4	E4	6yrs	Mch	1.8	4.3	1.8	4.3	45	34	20	32
5	E5	8yrs	Mch	1.5	4.0	1.5	4.0	52	40	27	37
6	E6	10yrs	Mch	1.8	4.3	1.9	4.4	44	30	15	26
7	E7	6yrs	Mch	1.9	4.4	1.9	4.4	52	38	14	28
8	E8	7yrs	Fch	1.7	4.2	1.7	4.2	60	46	10	23
9	E9	10yrs	Mch	1.9	4.4	1.9	4.4	61	45	5	18
10	E10	10yrs	Mch	1.9	4.4	2.0	4.5	65	49	14	24
11	E11	8yrs	Mch	1.5	4.0	1.6	4.1	68	54	11	24
12	E12	6yrs	Fch	1.5	4.0	1.5	4.0	66	51	14	25
13	E13	10yrs	Fch	1.7	4.2	1.7	4.2	60	47	18	29
14	E14	10yrs	Mch	1.9	4.4	1.9	4.4	55	42	21	30
15	E15	8yrs	Mch	1.7	4.2	1.7	4.2	57	42	15	26

Ph : 0091 - 04288 - 260032, 260588

J.K.K.MUNIRAJAHH MEDICAL RESEARCH FOUNDATION
COLLEGE OF OCCUPATIONAL THERAPY

Ethirmedu, B.Komarapalayam - 638 183. Namakkal Dist, Tamilnadu, India.
Wedsite : www.jkkm.org, e-mail : jkkm_kpm@yahoo.com

Rtn. MPHF. **Dr. J.K.K. MUNIRAJAHH** M.Tech., (Bolton)
Correspondent

MOT/Project-Permission/2017

Date : 19.08.2017

To
Mr.Manivannan,
Programme Manager,
Parti Project,
The Leprosy Mission Trust India,
Chidambaram.

Respected Sir/Madam,

Sub: Regarding permission to project data collection.

* * *

With reference to the subject cited above, our Master of Occupational Therapy Second year student **ILAVARASI.K.** is doing project on the topic "Study on Effectiveness of 3D Foot Analyser Insole in the Management of Children with Flat Foot". She likes to collect data from your centre. So, we request you to give permission for the above student to collect the data for her project.

Thanking you,

Yours sincerely,

G. Jegadeesan

PRINCIPAL
JKKMMRF COLLEGE OF
OCCUPATIONAL THERAPY
KOMARAPALAYAM - 638 183

Okay
25/08/17

PARTI PROJECT
2/181, M.I. Nagar,
Chidambaram
Cuddalore Dist. 608 001.
Tamilnadu
Ph : 04144-231405,
Mob.: 8074311405
THE LEPROSY MISSION TRUST

CONFIDENTIALITY

Your name will not be associated with the results in this study. It will be issued for both teaching and research purpose. Only myself and my guide will have access to the name of the subjects participating in this study.

The following is the name address and telephone number of the person to be contacted in event of research related inquiry.

Name : K. ILAVARASI.

Address : JKKMMRF College of Occupational Therapy

Komarapalayam, Namakkal Dt.

CONCERN TO PARTICIPATE VOLUNTARILY IN A RESEARCH INVESTIGATION

NAME:

AGE:

SEX

ADDRESS FOR COMMUNICATION:

DECLARATION:

I have fully understood the nature and purpose of the study. I accept my child to be a subject in this study. I declare that the above information is true to my knowledge.

Signature of the informant

Date:

Place: